IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NORTH DAKOTA

ABBVIE INC. (a Delaware corporation); ALLERGAN, INC. (a Delaware corporation); DURATA THERAPEUTICS, INC. (a Delaware corporation); ABBVIE PRODUCTS LLC (a Georgia limited liability company); PHARMACYCLICS LLC (a Delaware limited liability company); ALLERGAN SALES, LLC (a Delaware limited liability company),

Plaintiffs,

v.

DREW H. WRIGLEY, in his official capacity as ATTORNEY GENERAL OF THE STATE OF NORTH DAKOTA,

and

TANYA L. SCHMIDT, in her official capacity as BOARD PRESIDENT OF THE NORTH DAKOTA BOARD OF PHARMACY; and CAROLYN BODELL, TYLER G. LANNOYE, SHANE R. WENDEL, KEVIN J. OBERLANDER, DIANE HALVORSON, and RON HORNER, in their official capacities as MEMBERS OF THE NORTH DAKOTA BOARD OF PHARMACY; and MARK J. HARDY, in his official capacity as EXECUTIVE DIRECTOR OF THE NORTH DAKOTA BOARD OF PHARMACY,

Defendant.

Case No. 1:25-cv-00081

FIRST AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

FIRST AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs AbbVie Inc., Allergan, Inc., Durata Therapeutics, Inc., AbbVie Products LLC, Pharmacyclics LLC, Allergan Sales, LLC (collectively "AbbVie" or "Plaintiffs"), by and through

their undersigned attorneys, bring this action for declaratory and injunctive relief against the Attorney General of the State of North Dakota and the Members of the North Dakota Board of Pharmacy, challenging the applicability and constitutionality of H.B. 1473, codified at N.D. Cent. Code § 43-15.3-08. In support, AbbVie alleges as follows:

PRELIMINARY STATEMENT

1. AbbVie brings this lawsuit to challenge the constitutionality of H.B. 1473—a recently enacted North Dakota law that requires AbbVie to transfer its pharmaceutical products unconditionally to certain commercial pharmacies at substantially discounted prices on pain of criminal penalties. In so doing, the law changes the terms of a federal drug-pricing regime—the federal 340B Program—and significantly increases the costs of participation in that regime. It also has the effect of regulating commerce occurring entirely outside North Dakota.

2. As such, H.B. 1473 effects an unconstitutional taking in violation of the Takings Clause of the Fifth Amendment. It also violates the Supremacy Clause by impermissibly adding state-law requirements for participating in the federal 340B Program. In addition, H.B. 1473 unlawfully discriminates against or unduly burdens interstate commerce and purports to regulate wholly out-of-state transactions in violation of the Commerce Clause.

3. H.B. 1473 arises out of a long-running dispute about the requirements that the federal 340B program—a drug-pricing scheme—places upon drug manufacturers. In short, the federal 340B statute, 42 U.S.C. § 256b, establishes a comprehensive program that requires pharmaceutical manufacturers to offer their drugs at statutorily set and significantly reduced prices to a list of fifteen specifically enumerated types of healthcare providers known as "covered entities." Opting into the 340B Program and making these offers of drugs at the significantly

reduced prices is required for manufacturers who want to participate in federal Medicaid and Medicare programs. *See* 42 U.S.C. §§ 256b, 1396r-8(a)(1), (5).

4. Under the 340B statute, manufacturers are required only to "offer" their drugs to covered entities at the 340B price—not "sell" them. 42 U.S.C. § 256b(a)(1). That is, the 340B statute requires only that manufacturers make an offer at a particular price to a particular set of covered entities but preserves the liberty of manufacturers to insist upon other non-price terms. And commercial pharmacies, like Walgreens and CVS, are not among the 340B statute's list of entities entitled to an "offer" of the 340B price.

5. For enforcement of its provisions, the 340B statute grants *exclusive* authority to the Secretary of the U.S. Department of Health and Human Services ("HHS"). *See* 42 U.S.C. § 256b(d). The statute leaves no role for states or other third parties to change the requirements of the federal 340B program or the conditions it imposes on manufacturers in return for participating in Medicaid and Medicare. Nor do states or other third parties have any authority to enforce the federal statute's requirements. The Supreme Court has held that third-party enforcement "would undermine the agency's efforts to administer" the 340B program and other related federal programs "harmoniously and uniformly." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 119–20 (2011).

6. Further, because outright forcing manufacturers to transfer their drugs at discounted prices to covered entities would raise serious constitutional concerns, Congress left the 340B Program voluntary—conditioned upon participation in Medicaid and Medicare. And to further incentivize manufacturer participation in 340B—i.e., to prevent the cost of participation from becoming too high—Congress carefully limited the program and adopted certain safeguards to ensure that manufacturers' discounted drugs would be used to help needy patients, rather than

become a buy-low, sell-high scheme for commercial entities. For example, in a statutory provision designed to prevent "diversion," Congress prohibited covered entities from transferring manufacturers' reduced-price drugs to anyone other than the entity's own patients. *See* 42 U.S.C. § 256b(a)(5)(B). In effect, that provision prohibits other commercial entities from either participating in the 340B program or profiting from the sale of manufacturers' drugs at the 340B discounted price.

7. Nevertheless, over the last decade covered entities have entered into novel contractual arrangements with commercial pharmacies (called "contract pharmacies") that have allowed those pharmacies to profit from the sale of manufacturers' drugs. Instead of serving the covered entities' uninsured and low-income patients, the for-profit contract pharmacies acquire manufacturers' drugs at the federally discounted price, sell them to patients (including indigent patients) at full price, and pocket the difference. Contract pharmacies accomplish this arbitrage through a complicated accounting system known as the "replenishment model," described in more detail below. The bottom-line result is that for-profit commercial pharmacies and the covered entities they contract with are able to pocket billions of dollars every year, splitting the profits at the expense of both manufacturers and the needy patients who are supposed to be served by the federal 340B program.

8. Neither contract pharmacies nor the replenishment model are features of the ordinary commercial drug-distribution system in the United States, outside the 340B context, where they are unauthorized by statute. AbbVie is involved in no other commercial arrangement using contract pharmacies or the replenishment model. Contract pharmacies and the replenishment model are creatures only of the federal 340B drug discount arbitrage regime.

9. In response to these abuses, manufacturers (including AbbVie) have adopted policies that limit when they will sell or facilitate the transfer of drugs at the 340B-discounted price to third-party commercial pharmacies. These policies recognize that the federal statute requires only that manufacturers "offer" their drugs at discounted prices to the covered entities ***themselves***. There is no additional requirement that manufacturers provide the drugs to whomever and wherever the covered entities may demand, and there is certainly no requirement that manufacturers allow commercial pharmacies to ***profit*** from the sale of their drugs at discounted prices under the federal 340B program.

10. Manufacturers' decisions to address these abuses resulted in litigation between manufacturers and the U.S. Department of Health and Human Services. In early 2023, the U.S. Court of Appeals for the Third Circuit confirmed that the manufacturers' policies are lawful and permitted under federal law. In short, commercial pharmacies are not covered entities, and they are not entitled to benefit from the federal 340B program or access manufacturers' drugs at the 340B-discounted price. *See Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696 (3d Cir. 2023). Congress required manufacturers to offer their drugs at discounted prices in return for participating in Medicaid and Medicare; it did not impose any additional obligation on manufacturers to provide their drugs to third-party commercial pharmacies, or to otherwise support arbitrage of their charitable discounts.

11. In May 2024, the United States Court of Appeals for the District of Columbia Circuit agreed with the Third Circuit's conclusion, holding that because "section 340B merely requires manufacturers to propose to sell covered drugs to covered entities at or below a specified monetary amount," the statute gives manufacturers freedom to impose conditions on their offers as long as the offers remain "bona fide." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460,

463 (D.C. Cir. 2024). And because conditions limiting contract pharmacies in no way impair a manufacturer's offer to sell drugs at the 340B-discounted price, the restrictions fall within the ambit of freedom manufacturers enjoy under the federal 340B statute. *Id.* at 462–64.

12. Many of North Dakota's sister states participated in the Third Circuit case as *amici curiae*, on the losing side. After that loss, many states turned to their own legislatures to propose and implement legislation to reach their desired 340B outcomes and attempt to impose requirements under the federal 340B statute that Congress chose not to impose. H.B. 1473 is an example of one such piece of legislation and goes beyond many statutes passed by North Dakota's sister states.

13. H.B. 1473 endeavors to undo the decisions Congress made in the 340B statute, and that the Third and D.C. Circuits have recognized in their recent decisions. In particular, H.B. 1473 compels AbbVie to transfers its drugs at the 340B price to commercial pharmacies and under conditions Congress did not impose and that AbbVie would not otherwise adopt. The state law's main provision says that a manufacturer may not "[d]irectly or indirectly deny, restrict, prohibit, or otherwise interfere with the ***acquisition of a drug by a contract pharmacy*** on behalf of a covered entity unless receipt of the drug is prohibited by law." H.B. 1473 § 1(b)(1) (emphasis added). The text of the law effectively transfers to covered entities ***and commercial pharmacies*** unfettered authority to demand manufacturers' property at significantly reduced prices for the benefit of private parties of their choice.

14. Through this provision and others, H.B. 1473 violates the United States Constitution and should be enjoined.

15. ***First***, H.B. 1473 deprives manufacturers of property without due process of law and results in an impermissible taking under the Fifth Amendment. Under the Fifth Amendment,

made applicable to the states through the Fourteenth Amendment, neither the federal government nor the states have any authority to force A-to-B transfers of private property for the benefit of private parties. *See Kelo v. City of New London*, 545 U.S. 469, 477 (2005) (explaining that "the sovereign may not take the property of A for the sole purpose of transferring it to another private party B, even though A is paid just compensation"). The federal government has defended the federal 340B statute on grounds that manufacturers are not being ***forced*** to transfer their property to for-profit pharmacies, but instead supposedly agreed to do so at the request of covered entities "voluntarily" in exchange for the benefit of participation in the federal Medicaid and Medicare programs. North Dakota has no such defense: the State offers no carrot, only the cudgel of civil penalties.

16. North Dakota purports to directly require manufacturers to transfer their property at steeply discounted prices to other private entities if those entities have ***third-party*** contracts that purport to allow them to access AbbVie's drugs at those deep discounts. H.B. 1473's text makes clear that it seeks to regulate the "acquisition of a drug," defined as a drug purchased at the federally regulated 340B-discounted price. *See* H.B. 1473 § 1(a)(3); *id.* § 1(b)(1). North Dakota has no authority to take private property for private use, and no authority to deprive AbbVie of its property without due process of law. By seeking to change the requirements for when drug manufacturers must provide 340B-priced drugs to third parties at the request of covered entities or pharmacies, the statute unlawfully appropriates private property for the private benefit of commercial pharmacies and does so without serving any valid public purpose. *See Horne v. Dep't of Agric.*, 576 U.S. 350, 370 (2015) (holding government's confiscation of portion of farmers' raisin crop for charitable or other purposes without just compensation was a *per se* taking).

17. ***Second***, even if H.B. 1473 does not effect a taking, it is preempted by federal law under the Supremacy Clause. Federal preemption requires that "any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." *Felder v. Casey*, 487 U.S. 131, 138 (1988)). By seeking to limit the federal "offer" requirements that manufacturers must make as a condition of participating in the federal Medicaid and Medicare programs, H.B. 1473 unlawfully modifies the requirements of the federal 340B program. H.B. 1473 impermissibly injects the North Dakota Attorney General and the Board of Pharmacy, armed with state law penalties and other remedies, into what Congress intended to be an exclusively federal scheme. And H.B. 1473 also conflicts with the objectives of the 340B statute, imposing requirements on drug manufacturers that conflict with the actual requirements of the 340B statute, thereby raising the costs of Medicaid and Medicare participation above those set by Congress and deterring manufacturers from that participation. H.B. 1473 also blocks manufacturers from requesting claims data for contract pharmacy dispenses. *See* H.B. 1473 § 1(b)(3). That impairs a liberty the 340B statute grants. And it prevents AbbVie from accessing the federal 340B administrative dispute resolution system ("ADR").

18. ***Third***, H.B. 1473 conflicts with the recently announced 340B Pilot Rebate Program. That Program contemplates that participating manufacturers will make the 340B price available through a rebate mechanism, and that to effectuate those rebates, manufacturers will request, and covered entities (and contract pharmacies) will provide, claims data. Yet H.B. 1473 purports to prohibit rebate mechanisms outright. H.B. 1473 § 1(b)(5). It also purports to prohibit AbbVie from collecting claims data from covered entities and contract pharmacies. *Id.* § 1(b)(3). As far as conflict preemption goes, that is as clear as it gets.

19. ***Fourth***, H.B. 1473 is unconstitutionally vague. "It is a basic principle of due process that an enactment is void for vagueness if its prohibitions are not clearly defined." *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972) (collecting cases). In determining whether a statute is constitutionally vague, a court evaluates (1) whether the statute gives fair warning to those who are potentially subject to it and (2) does the statute do an adequate job of guarding against arbitrary and discriminatory enforcement. For example, North Dakota's law criminalizes any manufacturer's attempt to "prohibit a contract pharmacy from dispensing a drug by denying access to the drug." H.B. 1473 §1(b)(2). But it remains entirely unclear what work that provision—which presumably carries a meaning different than the other provisions—is doing. AbbVie's policy has exactly no effect on patient access or any pharmacy's ability to access AbbVie's drugs at the commercial price. The policy only effects a contract pharmacy's ability to purchase drugs at the discounted 340B price, not the ability to purchase them at all. For another example, H.B. 1473 proscribes "interfer[ing] with the ability of a covered entity or contract pharmacy to dispense a drug to an ***eligible patient*** of the covered entity." H.B. 1473 § 1(b)(4). But manufacturers have no way of knowing what patient definition a covered entity or contract pharmacy applies to determine a patient's "eligibility" because they may select their own definition and need not disclose it. *See Genesis Health Care Inc. v. Bercerra et al*., 701 F. Supp. 3d, 312, 322 (D. S.C. 2023). And the provision contains no scienter requirement, meaning a manufacturer could arguably violate it even by accident.

20. ***Fifth***, H.B. 1473 violates the Commerce Clause, as interpreted by Supreme Court precedent applying the Dormant Commerce Clause doctrine. A state law cannot "directly regulate out-of-state transactions by those with no connection to the state." *Nat'l Pork Prods. Council v. Ross*, 598 U.S. 356, 376 n.1 (2023). H.B. 1473 purports to do exactly that, because nowhere in

the bill's text is there any requirement that the transactions it covers have ***any*** nexus to North Dakota. In fact, H.B. 1473, by its text, regulates conduct "within and outside this state[.]" *See* H.B. 1473, § 1(a) (defining "contract pharmacy" as "a pharmacy that has a contract with a covered entity to receive and dispense drugs to the covered entity's patients on its behalf"); *see also*, *id.* § 2(5) (defining "covered entity" by reference to the federal 340B statute, without limiting the definition to North Dakota covered entities). North Dakota is attempting to compel manufacturers to act in accordance with North Dakota law outside of North Dakota. This is not hypothetical: covered entities commonly enter contracts with pharmacies outside the state to extend and expand the arbitrage opportunities that the pharmacies present. Separately, "nondiscriminatory burdens on commerce . . . that . . . clearly outweigh the benefits of a state or local practice" also violate the Dormant Commerce Clause. *Dep't of Revenue of Ky. v. Davis*, 553 U.S. 328, 353 (2008) (citing *Pike v. Bruce Church Inc.*, 397 U.S. 137, 142 (1970)). The burden H.B. 1473 places on the national prescription drug industry and the viability of the 340B program is excessive in relation to any legitimate benefits North Dakota could reap from it, because there are none—the effect of the bill is to actually harm 340B patients.

21. AbbVie seeks a declaration that H.B. 1473 is unconstitutional because it constitutes an unconstitutional taking. AbbVie further seeks a declaration that H.B. 1473 is unconstitutional because it is preempted by federal law, is unconstitutionally vague, and violates the Commerce Clause. AbbVie further seeks injunctive relief barring the North Dakota Attorney General and the Board of Pharmacy from enforcing H.B. 1473 against AbbVie.

PARTIES TO THE ACTION

22. AbbVie, Inc., a Delaware Corporation, is a global research-based biopharmaceutical company dedicated to addressing some of the world's most complex and

serious diseases, and advancing medical science in areas such as immunology, oncology, and neuroscience. Since 2012, AbbVie, Inc. has participated in the federal 340B drug discount program, helping uninsured and vulnerable patients obtain access to the medications they need. AbbVie's headquarters are located in North Chicago, Illinois. AbbVie, Inc. is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with the U.S. Department of Health and Human Services ("HHS") Health Resources and Services Administration ("HRSA").[1]

23. Allergan, Inc., a Delaware Corporation, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

24. Durata Therapeutics, Inc., a Delaware Corporation, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

25. AbbVie Products LLC, a Georgia Limited Liability Company, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

26. Pharmacyclics LLC, a Delaware Limited Liability Company, is a new party to this lawsuit, and a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

[1] On February 11, 2025, President Trump issued Executive Order 14210, titled "Implementing the President's 'Department of Government Efficiency' Workforce Optimization Initiative. *See* 90 Fed. Reg. 9,669. On March 27, 2025, HHS announced it intended to restructure, including by creating an Administration for a Healthy America ("AHA") which will have authority over, among other sub-agencies, HRSA. *See* Dep't of Health & Human Servs., *HHS Announces Transformation to Make America Healthy Again* (March 27, 2025), https://www.hhs.gov/press-room/hhs-restructuring-doge.html.

27. Previously, Warner Chilcott Corporation merged with Allergan Sales, LLC and Allergan Sales, LLC is the surviving entity. Allergan Sales, LLC, a Delaware Limited Liability Company, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

28. Defendant Drew H. Wrigley is the Attorney General of the State of North Dakota. H.B. 1473 imposes criminal sanctions upon violation. *See* H.B. 1473 § 1(b). Such enforcement power falls within the enforcement authority granted to the Attorney General by the North Dakota legislature. *See* N.D. Cent. Code §§ 54-12-01(2); 54-12--02. This suit is brought against the Attorney General solely in his official capacity.

29. Defendants Tanya L. Schmidt, Board President of the North Dakota Board of Pharmacy; Mark J. Hardy, Executive Director of the North Dakota Board of Pharmacy; and, Carolyn Bodell, Tyler G Lannoye, Shane R. Wendel, Kevin J. Oberlander, Diane Halvorson, and Ron Horner, Members of the North Dakota Board of Pharmacy, also have authority to enforce violations of § 43-15.3-08, the subsection which H.B. 1473 amends. *See* N.D. Cent. Code. § 43-15.3-09. This suit is brought against the President, Executive Director, and Members of the North Dakota Board of Pharmacy in their official capacities.

JURISDICTION AND VENUE

30. AbbVie's causes of action arise under 28 U.S.C. § 1331, 42 U.S.C. § 1983, and the United States Constitution.

31. The Court has subject matter jurisdiction under 28 U.S.C. § 1331, 28 U.S.C. § 1332, and 28 U.S.C. § 1343(a)(3).

32. The Court has authority to grant injunctive and declaratory relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, and the Court's inherent equitable powers,

including the power to enjoin the actions of state officials if contrary to the United States Constitution or federal law. *See Ex parte Young*, 209 U.S. 123, 159–60 (1908).

33. Venue is proper in this District under 28 U.S.C. § 1391(b) because this action challenges a North Dakota law that is applicable to AbbVie's sale and distribution of drugs at discounted prices under the federal 340B statute within this District. AbbVie sells and distributes drugs to multiple 340B covered entities within this District, and these entities purport to maintain contract pharmacy arrangements. Venue is also proper because Defendants maintain offices, through which they would enforce the challenged law, in the city of Bismarck within this District.

GENERAL ALLEGATIONS

A. The 340B Drug Pricing Program

34. This case concerns section 340B of the federal Public Health Service Act, which created the federal "340B program" as part of the authority granted in the Veterans Health Care Act of 1992. *See* 42 U.S.C. § 256b; *see also* Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (1992).

35. The purpose of the federal 340B program is to "reduce pharmaceutical costs for safety-net medical providers and the indigent populations they serve" by creating "a low-cost source of pharmaceutical medication for the indigent patients themselves." Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program*, 57 Wm. & Mary L. Rev. 637, 638 (2015) (footnote omitted).

36. Before Congress created the 340B program, individual manufacturers voluntarily provided their drugs at reduced prices to institutions that served needy and vulnerable patients. In 1990, Congress passed a statute called the Medicaid Rebate Act, which had the unintended consequence of creating disincentives for manufacturers to continue providing those voluntary discounts. H.R. Rep. No. 102-384, pt. 2, at 9–10 (1992). Through the Veterans Health Care Act,

Congress remedied that unintended disincentive and established the federal 340B program, turning the manufacturers' previous voluntary support into a federal mandate.

37. The 340B statute requires that any manufacturer that participates in the federal Medicaid Drug Rebate Program must "offer" its covered outpatient drugs at significantly reduced prices to eligible "covered entities." 42 U.S.C. § 256b(a)(1). The statute expressly limits participation in the 340B program to "covered entities." *See id.* § 256b(a)(4). The statute defines "covered entities" to include fifteen types of healthcare providers receiving federal or state funds. The list includes, for example, federally qualified health centers, children's hospitals, qualifying rural hospitals, and clinics that serve vulnerable patients. *Id*. For-profit commercial pharmacies are not included in the statutory list of "covered entities." *Id*. Nor does the 340B statute include any provision authorizing covered entities to purchase manufacturers' drugs and dispense them through commercial pharmacies. *See AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 60 (D. Del. 2021) ("It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication."), *aff'd sub nom. Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 703 (3d Cir. 2023).

38. The discounted 340B price for each of the manufacturer's drugs is calculated by subtracting the drug's Medicaid unit rebate amount from its Average Manufacturer Price, as determined under the federal Medicaid Drug Rebate Program, codified at section 1927 of the Social Security Act. 42 U.S.C. § 256b(a)(1)–(2) & (b). The resulting prices, called the 340B "ceiling prices," are significantly lower than the prices at which manufacturers sell their products to other purchasers. For the vast majority of innovator drugs, the mandatory discounts range from at least 23.1% to more than 99.9% of the average price in the market. *See* 42 U.S.C. § 1396r-8(c);

42 U.S.C. § 256b(a)(1). Many mandatory 340B ceiling prices are as little as one penny per unit of drug.

39. To indicate their agreement to participate in the federal 340B program and comply with its requirements, manufacturers sign a form contract with HHS, called the Pharmaceutical Pricing Agreement ("PPA"). That agreement is drafted by HHS. It has "no negotiable terms," and it "incorporate[s] the statutory obligations and record[s] the manufacturers' agreement to abide by them." *Astra*, 563 U.S. at 117–18.

40. The PPA imposes no obligation on participating manufacturers to sell discounted drugs to contract pharmacies. Nor does the PPA require manufacturers to cause their discounted drugs to be transferred to contract pharmacies. Nor does it grant covered entities any right to obtain access to manufacturers' drugs at discounted prices through contract pharmacies.

41. Both the PPA and the federal 340B statute are structured to prevent commercial parties from participating in the federal 340B program or profiting from the sale of manufacturers' drugs at discounted prices. Over the past decade, however, that is exactly what has happened as a result of covered entities entering into contractual relationships with commercial pharmacies. Under these arrangements, instead of using manufacturers' deeply discounted drugs to treat the indigent and uninsured patients that visit a covered entity and receive healthcare services from the covered entity itself, commercial contract pharmacies sell manufacturers drugs at regular prices to pharmacy customers and then demand that their stocks be replenished with drugs purchased by the covered entity through the federal 340B program at discounted prices, pocketing the difference (the "spread") for their own financial benefit.

42. In recent years, commercial contract pharmacies have earned annually over $3.3 ***billion*** in "spread." *See* Eric Percher et al., Nephron Rsch. LLC, *The 340B Program Reaches a*

Tipping Point: Sizing Profit Flows and Potential Disruption, at 3, 30–31 (2020) (concluding that $3.348 billion in 340B discounts were retained as profit by contract pharmacies in 2020 alone).

43. These abuses of the federal 340B program raise obvious concerns because the U.S. Constitution prohibits the government from forcing the transfer of property at confiscatory prices to private parties for their own private benefit. *See* U.S. Const. amend. V. They also violate the letter and spirit of the federal 340B statute. Congress designed the 340B statute with the intent that there would be a close nexus between the federal drug pricing program and its only valid public purpose—helping low-income and uninsured patients obtain access to medications at discounted prices. Consistent with that intent, the statute prevents covered entities from using manufacturers' drugs to generate commercial profits or letting the drugs be transferred or sold to benefit entities outside the program.

44. The statute expressly forbids "diversion" by prohibiting covered entities from selling or otherwise transferring any manufacturer's discounted drugs "to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B) ("With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity").

45. The statute also prohibits covered entities from receiving or causing "duplicate discounts or rebates." They may not obtain a 340B discount and cause a Medicaid rebate to be paid by the manufacturer for the same unit of drug. *Id*. § 256b(a)(5)(A).

46. The statute imposes an affirmative duty on the Secretary of HHS—through authority delegated to HRSA—to protect the program's integrity by "provid[ing] for improvements in compliance by covered entities . . . in order to prevent diversion" and violations of the statute's duplicate discount prohibition. *Id.* § 256b(d)(2)(A).

47. The statute provides mechanisms for resolving administrative disputes between manufacturers and covered entities through audits and a federal Administrative Dispute Resolution ("ADR") process. *See id.* § 256b(d)(l)(B)(v), (d)(3). Notably, HHS's HRSA recently issued a final rule setting forth additional details of the congressionally prescribed 340B ADR process. *See* 89 Fed. Reg. 28,643 (April 19, 2024). The final rule established a comprehensive scheme to resolve disputes between manufacturers and covered entities arising under the 340B statute. Under the rule, a "340B ADR Panel" within HRSA is tasked with resolving not only disputes about drug prices but also "claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price"—the exact issue H.B. 1473 seeks to address. *See* 42 C.F.R. §§ 10.3, 10.21; *accord id.* § 10.22(c)(1) ("A manufacturer is responsible for obtaining relevant information or documents from any wholesaler or other third party that facilitate the sale or distribution of its drugs to covered entities."); 89 Fed. Reg. 28,649 (April 19, 2024) ("HHS agrees and has further modified § 10.21(a)(1) to further explain that an overcharge claim generally includes claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price."); *id.* at 28,644 ("[T]he 340B Program is related to drug pricing and drug distribution.").

48. The statute entrusts enforcement of the 340B statute *exclusively* to the Secretary of HHS and details what penalties may apply. *See* 42 U.S.C. § 256b(a)(5)(C)–(D), (d)(l)(B)(v), (d)(3). As the Supreme Court reasoned in *Astra*, Congress made HHS administrator of both the Medicaid Drug Rebate Program and the 340B program, and private enforcement by covered entities "would undermine the [HHS's] efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Astra*, 563 U.S. at 119–20.

49. The 340B statute provides no private right of action to covered entities. *Id.* at 113–14.

50. Failure to comply with the statutory requirements under the 340B program may result in termination of the PPA (and the manufacturer's ability to participate in Medicaid), federal enforcement actions, and potentially the imposition of large civil penalties. *See* 42 U.S.C. § 256b(a)(5)(D), (d)(1)(B)(vi), (d)(2)(B)(v), (d)(3)(A).

B. The Growth in Contract Pharmacy Arrangements

51. In 1996, HRSA issued non-binding guidance stating that the agency would not prevent covered entities ***that lacked an in-house pharmacy*** from entering into a contractual relationship with a ***single*** outside pharmacy to dispense covered outpatient drugs to the covered entity's patients. 61 Fed. Reg. 43,549 (Aug. 23, 1996). The guidance made clear that it "create[d] no new law and create[d] no new rights or duties." *Id.* at 43,550.

52. Guidance documents, such as the 1996 guidelines, are by definition general statements of policy that are non-binding, non-enforceable, and do not create any legal rights or obligations. They are intended instead to inform the public as to how HRSA intends to exercise its enforcement discretion.

53. In 2010, HRSA issued new non-binding guidance that radically changed how covered entities operated under the 340B program. The guidance stated, for the first time, that the agency would allow covered entities to enter into contractual relationships with an *unlimited* number of "contract pharmacies," even if the covered entity had an in-house pharmacy of its own. 74 Fed. Reg. 10,272 (Mar. 5, 2010).

54. Like the 1996 guidance, the 2010 guidance did not impose binding obligations on manufacturers. Indeed, HRSA again made clear that the non-binding guidance created no new rights and imposed no new obligations. *See id.* at 10,273 ("This guidance neither imposes

additional burdens upon manufacturers, nor creates any new rights for covered entities under the law"). In other words, while HRSA indicated that it would not interpret the 340B statute to prohibit covered entities from using multiple contract pharmacies, it did not purport to impose any obligation on manufacturers to transfer drugs to contract pharmacies or otherwise facilitate covered entities' use of contract pharmacies.

55. Following issuance of the 2010 guidance, covered entities dramatically increased their use of contract pharmacies, with a recent study reporting an increase of 12,000% between 2010 and 2024. *See* Elanor Blalock, *For-Profit Pharmacy Participation in the 340B Program: 2024 Update*, BRG 7 (Jan. 2025) ("BRG Report"), https://tinyurl.com/2k8daabf. This explosion in the use of contract pharmacies has been driven by the prospect of sharing in the outsized profit margins on manufacturer-subsidized 340B drugs. For example, in 2009 340B drug sales totaled just $4.2 billion, but by 2023 had increased by more than 30-fold to $124 billion. *See* Karen Mulligan, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*, USC Schaeffer Cntr. For Health Pol'y & Econ. 5 (Oct. 2021) ("Mulligan"), https://tinyurl.com/y2fuv87u; Rory Martin & Harish Karne, *The 340B Drug Discount Program Grew to $124B in 2023*, IQVIA 2 (2024), https://tinyurl.com/ywkdbbju.

56. Similarly, the number of covered entities participating in the program jumped from around 15,000 in 2010 to more than 50,000 by 2020. *See* Mulligan, *supra*, at 4; U.S. Gov't Accountability Off., *Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*, GAO-20-108, at 23 (2019), https://www.gao.gov/assets/d20108.pdf ("Given the weaknesses in HRSA's oversight, some hospitals that do not appear to meet the statutory requirements for program eligibility are participating in the 340B Program and receiving discounted prices for drugs for which they may not be eligible.").

57. Nor does the program's explosive growth correlate with an increase in indigent patients, or improvements in care. Indeed, since 2010, the percentage of uninsured patients in the United States has fallen by nearly 38%. *See* Kenneth Finegold et al., U.S. Dep't of Health & Hum. Servs., Off. of the Assistant Sec'y for Planning & Evaluation, Trends in the U.S. Uninsured Population, 2010–2020, Issue Brief No. HP-2021-02, at 2 (Feb. 11, 2021), https://tinyurl.com/4rf9cm8t.

58. Contract pharmacies, which are predominantly large commercial pharmacy chains, do not operate like in-house pharmacies, do not themselves qualify as covered entities, and do not owe fiduciary duties to the covered entities. The relationships between covered entities and the for-profit, commercial pharmacies are governed by arm's-length contracts. Contract pharmacies are not "agents" of the covered entities; they are merely business partners. Importantly, these arrangements do not exist outside the context of the federal 340B program, as there is no other context in which commercial pharmacies are able to share in the "spread" generated by selling manufacturers' discounted drugs to their customers at full prices.

59. Contract pharmacy arrangements generally use one of two inventory models: (1) pre-purchased inventory or (2) replenishment.

60. A few contract pharmacies use the pre-purchased inventory model, in which a covered entity's 340B-purchased drugs are kept in stock at the contract pharmacy, and when filling prescriptions on behalf of that covered entity, the contract pharmacy uses the covered entity's 340B-purchased inventory.

61. Most contract pharmacies, however, use what is known as the "replenishment" model. The replenishment model is, as covered entities self-describe it, "an accounting mechanism" by which they retroactively match discounts for the pharmacy with previously (full

price) dispensing events to customers. *See AbbVie et al. v. Murrill*, No. 6:23-CV-01307-RRS-CBW (W.D. La. June 6, 2024) ("*Murrill*"), Summ. J. Hr'g Tr. at 59-60 (Ron Connelly, counsel for the Louisiana Primary Care Association); 61 Fed. Reg. 43,549, 43,555 (Aug. 23, 1996). In practice, the replenishment model permits the "transfer" of 340B-priced drugs to contract pharmacies with the full knowledge that those drugs will be sold to any customer who comes in the door, whether 340B-eligible or not.

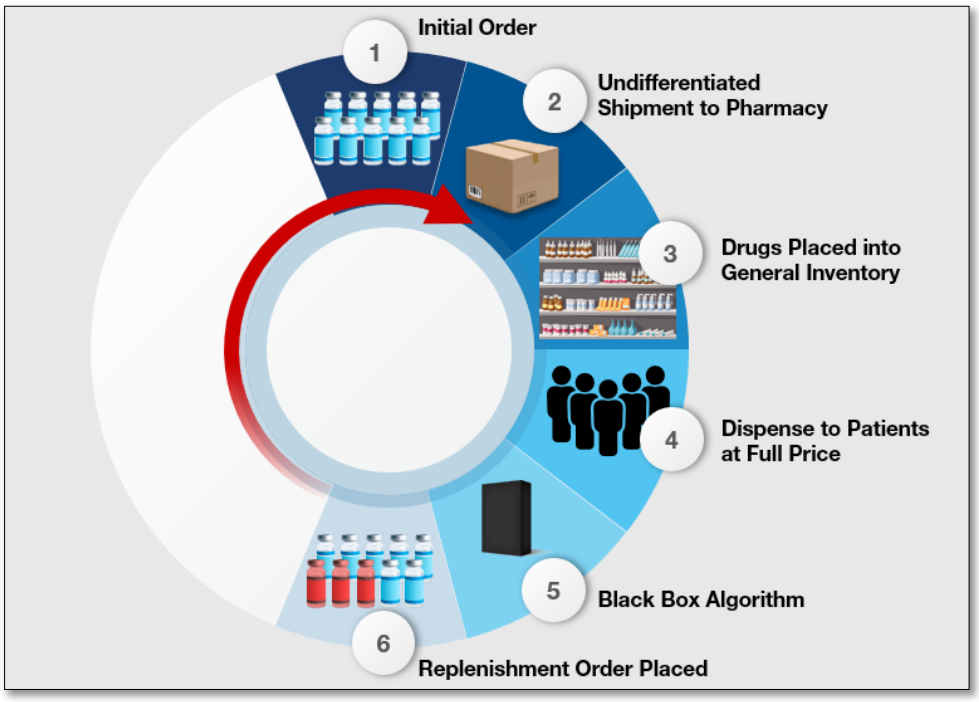

Figure 1. Replenishment Model Step-By-Step.

62. Under the replenishment model, no 340B-purchased drugs are kept in stock at the contract pharmacy. Instead, "the pharmacy has an initial stock of drugs" obtained through ordinary commercial purchases at the non-340B price (Figure 1, step 1). *See Murrill*, Summ. J. Hr'g Tr. at 60 (Ron Connelly, counsel for the Louisiana Primary Care Association). Initially, the contract pharmacy fills all prescriptions using its own non-340B purchased inventory (that is, full price inventory)—including those prescriptions issued by covered entities. As explained below, the

pharmacy determines which previous dispenses were 340B eligible and once sufficient eligible dispenses for a particular drug accumulate, the covered entity orders additional quantities of that drug at the federal 340B price (Figure 1, step 6). The covered entity directs AbbVie to transfer those drugs to the contract pharmacy to "replenish" the non-340B-priced drugs dispensed by the contract pharmacy on the covered entity's behalf (Figure 1, step 2). *See* Decl. of RADM Krista M. Pedley, Dir., Off. of Pharmacy Affs., HRSA, *Eli Lilly & Co. v. Becerra*, No. 1:21-cv-00081-SEB-MJD, ECF No. 125-2 ¶¶ 3–11 (S.D. Ind.). Sometimes the contract pharmacy actually places the order on behalf of the covered entity for more drugs at the federal 340B price.

63. Once the contract pharmacy receives the replenishment order, the 340B-priced drugs are "placed on the shelf, become[] 'neutral inventory,' and may be dispensed to any subsequent patient" (Figure 1, step 3). *See id.* at ¶ 11.

64. In other words, under the replenishment model, contract pharmacies do not keep a separate inventory of 340B-priced drugs but instead dispense drugs to both 340B and non-340B patients alike out of their general inventories. Nor do most contract pharmacies attempt to determine prior to or at the point of sale whether the patient is eligible for a 340B discounted drug. In almost all instances, contract pharmacies dispense the 340B-priced drugs to their customers at full price without knowledge as to whether, at the time of dispensing, that patient is a 340B-eligible patient (Figure 1, step 4). The pharmacy or a third-party administrator ("TPA") carries out a 340B determination at the back end, well after a drug has been dispensed (and likely consumed) by the patient. This determination is made using a black box algorithm (unknown by AbbVie) based on the contract pharmacy's own criteria, without any involvement from the covered entities (Figure 1, step 5). If those criteria are designed correctly, the post-sale determination may be able to calculate how many 340B-priced drugs AbbVie must sell. But in reality, the contract pharmacies'

criteria often include prior patients, who no longer receive the 340B-discounted drugs at the pharmacy but that are included under a "once-a-patient-always-a-patient" approach, so the covered entity and its pharmacies are able to maximize the arbitrage profits from the 340B program. As the D.C. Circuit observed, "[t]he covered entity, the pharmacy, and the third-party administrator often divvy up the spread between the discounted price and the higher insurance reimbursement rate. Each of these actors thus has a financial incentive to catalog as many prescriptions as possible as eligible for the discount." *Novartis*, 102 F.4th at 457–58.

65. Aside from diversion created by the pharmacies and covered entities' use of their own distorted criteria to mark otherwise 340B-ineligible sales as deserving the federally mandated low prices, the replenishment model encourages diversion by allowing covered entities to transfer federally discounted drugs to pharmacies, who are not "a patient of the entity." *See* 42 U.S.C. § 256b(a)(5)(B). Although HRSA interpreted the federal 340B statute to allow the use of pharmacies, it did so because "[w]e believe that the relationship between the covered entity and the contract pharmacy is one of agency." 61 Fed. Reg. 43,549, 43,554 (Aug. 23, 1996). Additionally, HRSA noted that the covered entity purchases the drug, retains title and responsibility for the drug even after directing shipment to the contract pharmacy. *Id.* at 43,553.

66. However, covered entities do not retain title to the drugs. As explained above, contract pharmacies (typically through a TPA) instruct covered entities to place orders—sometimes even placing the order itself, without going through a covered entity—of additional quantities of drugs at the discounted 340B price to "replenish" the general inventories that they will use to supply non-340B-eligible sales. Significantly, as a result of such replenishment, even though the drugs are purchased by or on behalf of covered entities, contract pharmacies effectively take title to the drugs. At no point in time does a covered entity take title to the drugs under this

model. *See Sanofi Sues HHS, HRSA for Contract Details Between Covered Entities, Contract Pharmacies*, 340B Report (June 18, 2024), https://tinyurl.com/bdmx88wu (according to a covered entity spokesperson, "in order for the replenishment model to work, 'the title to 340B drugs transfers to the contract pharmacy at the time it is taken into inventory.'"). AbbVie is also not aware of any instance where a contract pharmacy or covered entity represents that an agency relationship exists between them such that the contract pharmacy acts at the direction of a principal covered entity.

67. In practice, therefore, covered entities and contract pharmacies share in the "spread" generated by selling the drugs at higher prices to pharmacy customers and/or seeking full commercial reimbursement from the patients' insurance plans. For-profit, commercial pharmacies thereby obtain significant profits from selling the 340B covered outpatient drugs that manufacturers must offer to covered entities at deeply discounted prices.

68. By dramatically expanding the pool of individuals who can access the discounted drugs that covered entities can buy at discounted prices—including individuals who do not qualify as patients of the covered entity—covered entities and commercial pharmacies can obtain profits that extend far beyond Congress's intent when it created the 340B program. One study found that in 2018 alone, covered entities and their contract pharmacies generated approximately $64 billion in estimated gross profits from the purchase of manufacturers' drugs at mandated 340B prices. *See* BRG Report, *supra*, at 7.

69. When commercial pharmacies are brought into the program, there is a significantly greater risk that manufacturers' discounted drugs will be dispensed to individuals who are not "patients" of the covered entity. As HHS has found, contract pharmacy arrangements "create complications in preventing diversion" (for example, contract pharmacies cannot verify patient

eligibility in real-time like a covered entity can). HHS Office of Inspector General, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 1 (2014) ("HHS Report"), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.

70. Because contract pharmacies often dispense 340B covered outpatient drugs from the same inventory as drugs dispensed to all other customers (and seek replenishment after the fact), the opportunities for unlawful distributions to ineligible patients increases, allowing covered entities and contract pharmacies to profit from the diversion that Congress intended to prohibit. *See* U.S. Gov't Accountability Off., *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480, at 44 (June 2018), https://www.gao.gov/assets/d18480.pdf (noting that approximately two-thirds of diversion findings in HRSA audits involved drugs distributed at contract pharmacies); *id.* at 35, 43–44 (finding 45% of covered entities that responded to a recent GAO survey admitted they do not provide any discount to patients who use their contract pharmacies; and many of the remaining 55% reported rarely giving discounts to patients obtaining medicines through contract pharmacies).

71. Covered entities and commercial pharmacies reap windfalls from gaining access to manufacturers' drugs at deeply discounted prices under the federal 340B program, but uninsured and underinsured patients are not benefitting. *See* HHS Report, at 2 (finding that "some covered entities in our study do not offer the discounted 340B price to uninsured patients at their contract pharmacies"); Adam J. Fein, *The Federal Program that Keeps Insulin Prices High*, Wall. St. J. (Sept. 10, 2020), https://tinyurl.com/yxehpc7v (explaining that "almost half the U.S. pharmacy industry now profits from the 340B program, which is designed as a narrow support to certain hospitals," while patients "don't benefit," even though manufacturers have "practically given the

product away"); Rory Martin & Kepler Illich, *Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?*, IQVIA 12 (Sept. 27, 2022), https://tinyurl.com/2wdtuh52 ("The 340B Drug Discount Program as it exists today is a complex system of arbitrage . . . in which most vulnerable patients at contract pharmacies do not get drug discounts."); Lin JK et al., *Assessment of US Pharmacies Contracted with Health Care Institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics*, JAMA Health Forum 2 (June 17, 2022), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2793530 (finding that contract pharmacy growth from 2011–2019 was concentrated in affluent and predominantly White neighborhoods and that the share of 340B pharmacies in socioeconomically disadvantaged and primarily non-Hispanic Black and Hispanic/Latino neighborhoods declined).

72. For example, the North Carolina Department of the State Treasurer published a recent report explaining that "some hospitals are using the 340B program to enrich themselves rather than to serve vulnerable communities," and "instead . . . expanded into wealthier neighborhoods with a higher percentage of insured individuals who pay more for the drugs." Dale R. Folwell, N.C. Dep't of State Treasurer, *Overcharged: State Employees, Cancer Drugs, and the 340B Drug Pricing Program*, N.C. State Health Plan 3, https://tinyurl.com/4cy8an69.

73. While commercial pharmacies are driving massive growth in the 340B program—at double-digit annual rates—charity care by hospitals has decreased. Commentators have noted, for example, that as the 340B program has grown at a remarkable rate, the total value of hospitals' uncompensated care has significantly declined. *See* Letter from Adam J. Fein to Hon. Lamar Alexander and Hon. Greg Walden in response to request for input on 340B drug pricing program, 7–8 (Oct. 30, 2020), https://drugchannelsinstitute.com/files/AdamFein-DrugChannels-340B-

30Oct2020.pdf; Adam J. Fein, *EXCLUSIVE: 340B Program Purchases Reach $24.2 Billion—7%+ of the Pharma Market—As Hospitals' Charity Care Flatlines*, Drug Channels (May 14, 2019), https://tinyurl.com/4z8dmjsv.

74. Both the New York Times and Wall Street Journal have run exposés describing the flaws in contract pharmacy arrangements, flaws that enable large scale arbitrage and damage the very communities that the federal 340B program was designed to help. *See* Katie Thomas & Jessica Silver-Greenberg, *Profits Over Patients: How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, NY Times (Sept. 24, 2022), https://tinyurl.com/3sbxuswa (describing how one 340B hospital "has been slashing services at Richmond Community while investing in the city's wealthier, white neighborhoods, according to more than 20 former executives, doctors and nurses"); Anne Wilde Mathews et al., *Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients*, Wall. St. J. (Dec. 22, 2022), https://tinyurl.com/yc2uc6yp ("The data show that hospitals often extend their 340B discounts to clinics in well-off communities, where they can charge privately insured patients more than those on Medicaid" which "raise questions about the program's growth and purpose").

75. A recent New York Times investigation into Apexus, the government contractor managing 340B drug pricing, exposed systemic price manipulation, lack of oversight, and financial exploitation within contract pharmacy arrangements—allowing for significant financial abuse at the expense of the communities the program was meant to protect. Apexus, which is responsible for negotiating better prices and access to mediations, has a direct financial incentive to expand the program and maximize hospital profits. Because Apexus "is allowed to collect a fee for almost every drug sold under the program," it has actively developed strategies to drive 340B sales and increase covered entity revenue. These strategies include training covered entities on how to

maximize 340B revenue; operating a "purchasing optimization team" advising hospitals on which drugs to generate the highest margins; and running a certification program teaching hospitals how to capture more patients and prescriptions under 340B. These tactics have prioritized profit generation over patient benefit, increasing Apexus's and covered entities' financial gains at the expense of patients, insurers, and manufacturers. Hospitals face no restrictions on which outpatient prescriptions they classify as 340B, allowing them to mine patient records from as far back as 36 months to claim additional patients under the program—even if those patients never directly benefit from the discounts. In some cases, hospitals have passed inflated drug costs onto patients instead of sharing the savings. *See* Ellen Gabler, *How a Company Makes Millions Off a Hospital Program Meant to Help the Poor*, N.Y. Times (Jan. 15, 2025), https://tinyurl.com/33ftpfdf.

C. Manufacturers' Response to HRSA's Overreach

76. AbbVie and other manufacturers have exercised their lawful right to decline covered entity requests that manufacturers provide their discounted 340B-priced drugs to an unlimited number of commercial pharmacies.

77. AbbVie has implemented initiatives making clear that it will not indiscriminately accept requests that it transfer 340B-discounted drugs to an unlimited number of third-party commercial contract pharmacies servicing covered entities.

78. As 340B abuse continued to grow, with covered entities seeking the provision of 340B-priced drugs to an excessive number of for-profit pharmacies—sometimes located more than 100 miles from the covered entity's location—AbbVie updated its policy to place reasonable limits around provision to contract pharmacies. Specifically, if a covered entity has its own in-house pharmacy, AbbVie's policy now is to only take orders for the in-house pharmacy. However, if a covered entity does not have an in-house pharmacy capable of dispensing to outpatients, AbbVie

will take orders for one designated contract pharmacy, provided that the one contract pharmacy is located within 40 miles of the HRSA registered covered entity parent site, and the covered entity submits limited claims data on 340B utilization for that pharmacy location. In addition, Grantee Covered Entities may use an unlimited number of contract pharmacies as long as the Grantee registers with 340B ESP™, a web-based platform made available to covered entities at no cost, and submit claims data.[2] *See* Ltr. from E. Scheidler to 340B Covered Entities (Feb. 27, 2025), https://tinyurl.com/mr2rac4u.

79. In implementing its initiatives, AbbVie has confirmed that it will continue to offer "each covered entity" the ability to "purchase" its covered outpatient drugs "at or below the applicable ceiling" price set by statute. *See* 42 U.S.C. § 256b(a)(1). AbbVie is committed to ensuring that each hospital covered entity has at least one pharmacy location where it can receive shipments of discounted AbbVie medicines, and out of which it can dispense AbbVie's 340B-discounted drugs to qualifying patients. If a hospital covered entity is unable to identify an eligible contract pharmacy within 40 miles, AbbVie will work with the covered entity to identify a suitable alternative.

80. In addition to AbbVie, many other pharmaceutical manufacturers have adopted policies directed at addressing abuses of the 340B program by covered entities and contract pharmacies. Like AbbVie's, these policies do not refuse to supply drugs at discounted prices under the federal 340B program solely because the covered entity has an arrangement with a number of contract pharmacies; instead, they are directed at addressing program abuses.

[2] "Claims data," as used in the administration of the 340B program, refers to prescription-level information necessary to determine whether a drug is subject to a 340B discount, a Medicaid rebate, or both, and whether the recipient is a patient of a covered entity.

81. AbbVie's policy is not only consistent with those upheld by the Third and D.C. Circuits but also gives covered entities and contract pharmacies more convenience at its own expense. *See Sanofi*, 58 F.4th at 701; *Novartis*, 102 F.4th 452 at 463–64.

82. AbbVie's compelled compliance is directly attributable to North Dakota's enactment of H.B. 1473, which is set to come into effect on August 1, 2025.

D. Litigation in Federal Courts

83. HHS initially recognized that it lacked authority to compel manufacturers to transfer drugs to contract pharmacies. *See* Tom Mirga, HRSA Says Its 340B Contract Pharmacy Guidance Is Not Legally Enforceable, 340B Report (July 9, 2020), https://340breport.com/hrsa-says-its-340b-contract-pharmacy/. HHS then reversed its position and attempted to impose a new obligation on manufacturers.

84. On December 30, 2020, HHS issued a final decision—labeled an "Advisory Opinion"—that for the first time ever purported to require manufacturers to facilitate the transfer of their products to for-profit commercial pharmacies. *See* U.S. Dep't of Health & Hum. Servs., Advisory Op. No. 20-06, Contract Pharmacies Under the 340B Program 1 (Dec. 30, 2020), https://tinyurl.com/35n4szy6. Various manufacturers brought suit in early 2021 to challenge this HHS decision.

85. On May 17, 2021, the government sent certain manufacturers "violation" letters purporting to enforce the 340B statute. AbbVie received a violation letter on October 17, 2022, stating that HHS had made a final determination that AbbVie's policy violated the 340B statute by not agreeing to transfer 340B discounted drugs to unlimited contract pharmacies because "AbbVie's actions have resulted in overcharges." *See* U.S. Dep't of Health & Hum. Servs., Violation Letter to AbbVie (Oct. 17, 2022), https://tinyurl.com/47ybp3kw.

86. While the December 30 decision was later withdrawn following a ruling from the federal district court for the district of Delaware, *see AstraZeneca*, 543 F. Supp. 3d at 47, the previously issued violation letters were not withdrawn.

87. Multiple states, through their Attorneys General, filed amicus briefs in the Third and D.C. Circuit Courts of Appeals in support of HHS, expressing disapproval of the manufacturers' policies. *See* Corrected Brief of Amicus Curiae States, *Novartis*, 102 F.4th 452 (No. 21-5299, filed May 23, 2022); Brief of Amicus Curiae, *Sanofi Aventis*, 58 F.4th 696 (3d Cir. 2023) (No. 21-3167, ECF No. 34).

88. On January 30, 2023, the Third Circuit issued a decision recognizing that Congress intentionally "chose not to" impose contract-pharmacy obligations on manufacturers, explaining that the federal 340B statute's plain text suggests that Congress intended "one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies." *See Sanofi*, 58 F.4th at 704.

89. The Third Circuit further found that manufacturers' policies do not prevent covered entities from participating in the 340B program or entering into contractual relationships with commercial pharmacies. Under manufacturers' policies, covered entities "can still buy and dispense unlimited discounted drugs by having them delivered to an in-house or contract pharmacy." *Id*. at 703.

90. The Third Circuit rejected the argument that manufacturers were not permitted to address program abuses, such as diversion and duplicate discounting, by imposing restrictions on when they will transfer drugs to commercial pharmacies.

91. On May 21, 2024, the District of Columbia Circuit issued its own opinion endorsing the same view, holding that "section 340B merely requires manufacturers to propose to sell

covered drugs to covered entities at or below a specified monetary amount." *Novartis*,102 F.4th at 460. As a result, as long as a manufacturer's conditions "neither precludes [it] from making a bona fide 'offer' nor increases its contract 'price'"—such as only "deliver[ing] section 340B drugs to a covered entity's in-house pharmacy or to a single contract pharmacy designated by the covered entity"—the condition is legitimate and may be enforced without running afoul of section 340B. *Id.* at 463–64.

92. In the face of those federal decisions, several states enacted their own laws trying to achieve what HHS could not. Those state laws—passed in Arkansas, Kansas, Louisiana, Maryland, Minnesota, Mississippi, Missouri, West Virginia, and others—try to limit manufacturers' ability to condition the federal offer by forcing them to transfer their drugs to an unlimited number of contract pharmacies at the 340B-discounted prices. A new round of federal litigation commenced. Manufacturers challenged the laws as unconstitutional on several grounds, and that litigation continues today.

93. The Eighth Circuit Court of Appeals upheld a state contract pharmacy law in Arkansas because the Court assumed that "[c]overed entities maintain title to the 340B drugs," and the "pharmacy becomes an agent of the covered entity." *Pharma. Res. & Manfs. of Am. v. McClain*, 95 F.4th 1136, 1142, 1144 (8th Cir. 2024). That is not true in North Dakota. Covered entities do not maintain title to 340B-discounted drugs provided to contract pharmacies, nor do contract pharmacies serve as the "agent of the covered entity." *Id.*

94. By contrast, the Southern District of West Virginia preliminarily enjoined West Virginia's contract pharmacy law, holding the law unconstitutionally conflicted with section 340B. *PhRMA v. Morrisey*, 2024 WL 5147643, at *7-12 (S.D. W. Va Dec. 17, 2024). Laws like North Dakota's H.B. 1473 regulate "price, not delivery." *Id.* at *8. Under such laws, "[t]he question is

only about what price the pharmacy and the covered entity will pay." *Id.* In other words, "the system is about delivery *at a given price*, not delivery *per se*." *Id.*

95. Other cases await decisions in district court, and multiple appeals are now pending before the United States Courts of Appeals for the Fourth and Fifth Circuits.

E. The North Dakota Law

96. After federal courts had already decided that the federal 340B statute grants manufacturers the freedom to adopt policies to combat abuse of the 340B program by contract pharmacies, North Dakota enacted a law that takes that freedom away.

97. The North Dakota Senate introduced H.B. 1473 on January 17, 2025. The bill passed both houses on March 25, 2025 and became law on April 4, 2025 when Governor Kelly Armstrong signed it into law. The bill is set to take effect on August 1, 2025.

98. The law begins with three definitions. First, a "contract pharmacy" means "a pharmacy that has a contract with a covered entity to receive and dispense drugs to the covered entity's patients on its behalf." H.B. 1473 § 1(a)(1). Second, a "covered entity" means "an entity participating or authorized to participate in a federal drug discount program under 42 U.S.C. 256b." *Id.* § 1(a)(2). Third, a "drug" means "a drug purchased under reduced pricing under [federal] section 340B … by a covered entity." *Id.* § 1(a)(3).

99. The law then prohibits five discrete acts by rendering them a "class B misdemeanor" if done by "a manufacturer, an agent or affiliate of that manufacturer, virtual manufacturer, or third-party logistics provider of a manufacturer's drugs." *Id.* § 1(b).

100. ***First***, the Act provides that a manufacturer shall not "[d]irectly or indirectly deny, restrict, prohibit, or otherwise interfere with the acquisition of a drug by a contract pharmacy on behalf of a covered entity unless receipt of the drug is prohibited by federal law." *Id.* § 1(b)(1). Here, the Act directly targets the decisions of the Third and D.C. Circuits holding that the federal

340B statute preserves the liberty of manufacturers to attach reasonable conditions to their offer of 340B-priced drugs to covered entities. *Sanofi Aventis*, 58 F.4th at 701; *Novartis*, 102 F.4th 452 at 463–64. And it compels a private-to-private wealth transfer by forcing manufacturers to hand over their products at a particular price that they would not otherwise transfer. By incorporating the 340B price into the term "drug," the defining feature of this subsection is the price at which it compels the transfer.

101. ***Second***, the Act says that a manufacturer may not "[p]rohibit a contract pharmacy from dispensing a drug by denying access to the drug." *Id.* § 1(b)(2). This subsection drives at the same aim as subsection one: it requires manufacturers to acquiesce in the transfer of their products at a particular price to commercial pharmacies.

102. ***Third***, the Act announces a manufacturer may not "[r]equire a covered entity or contract pharmacy to submit any claims, encounter, or utilization data as a condition for acquiring or receiving a drug, unless the claims, encounter, or utilization data sharing is required by federal law." *Id.* § 1(b)(3).

103. H.B. 1473 tries to prevent manufacturers from collecting basic data that covered entities are already generating and sharing with their third-party vendors. *See* H.B. 1473 § 1(b)(3). That same data will allow manufacturers to monitor illegal diversion and duplicate discounting. It is also the primary means by which manufacturers may access the audit and ADR process. For similar reasons, a federal West Virginia court has already preliminarily enjoined West Virginia's similar law containing a similar prohibition. *Morrisey*, 2024 WL 5147643, at *7-12. Further, and as detailed below, this provision directly interferes with manufacturers' ability to participate in a recently announced federal 340B pilot program. *See* §F.

104. ***Fourth***, the Act says a manufacturer may not "Interfere with the ability of a covered entity or contract pharmacy to dispense a drug to an eligible patient of the covered entity." *Id.* § 1(b)(4). This subsection is impossibly—and perhaps deliberately—vague. As such, it is not clear what conduct it prohibits and which it does not. To be clear, AbbVie's policy has no effect on patient access or any pharmacy's ability to access AbbVie's drugs at commercial prices.

105. ***Fifth*** and finally, the Act says a manufacturer may not "Offer or otherwise make available a drug in the form of a rebate, unless in the form of a discount at the time of sale and authorized under federal law." *Id.* § 1(b)(5). This subsection thrust North Dakota smackdab into the middle of an ongoing dispute about whether the federal 340B statute—which permits manufacturers to offer the 340B price either through a "discount" or "rebate," 42 U.S.C. § 256b(a)(1)—endows HHS with preapproval authority over discount and rebate mechanisms, or whether manufacturers may elect either option until HHS speaks to the issue through lawful means. *See Eli Lilly and Company et al. v. Kennedy et al*., No. 24-cv-3220 (D.D.C.); *Bristol Myers Squibb Company v. Kennedy et al.*, No. 24-cv-3337 (D.D.C.); *Sanofi-Aventis U.S. LLC v. U.S. H.H.S.*, No. 24-cv-3496 (D.D.C.); *Novartis Pharmaceuticals Corporation v. Kennedy et al.*, No. 25-cv-0117 (D.D.C.). And like the claims-data prohibition, this provision also directly interferes with manufacturers' ability to participate in a recently announced federal 340B pilot program. *See* §F.

106. In all, these subsections combine to require manufacturers to convey their drugs to commercial pharmacies at a particular price and under onerous conditions they would otherwise never accept.

107. For an enforcement mechanism, the law denotes any violation is a class B misdemeanor, presumably enforceable by the Attorney General under his general enforcement authority. N.D. Cent. Code §§ 54-12-01(2); 54-12-02. Further, the statute vests the State Board

of Pharmacy with authority to impose both civil penalties and injunctive relief. *See* H.B. 1473 § 1; N.D. Cent. Code Ann. § 43-15.3-09(1), (2). The law thereby establishes the Attorney General and State Board as parallel enforcement arms of 340B pricing and terms.

F. H.B. 1473 and the Inflation Reduction Act of 2022

108. The Inflation Reduction Act of 2022 established the so-called "Drug Price Negotiating Program" (DPNP). *See* 42 U.S.C. § 1320f.

109. The DPNP requires the Secretary of the U.S. Department of Health and Human Services to set a "maximum fair price" (or MFP) in Medicare for drugs selected under the DPNP. *See id.* § 1320f(a)(3).

110. If they want to continue participating in Medicare and Medicaid, manufacturers of "selected drugs" are obligated to make those drugs available at the "maximum fair price" to all eligible individuals, which generally includes drugs dispensed by hospitals and pharmacies that care for Medicare-covered individuals. *Id.* §§ 1320f(c)(2), 1320f-2(a)(3).

111. Failure to provide access to the "maximum fair price" can subject a manufacturer to significant civil monetary penalties that can reach into the millions of dollars per day. *Id.* §§ 1320f-6(c), 1320f-2(a)(5).

112. The Centers for Medicare & Medicaid Services (CMS)—the agency tasked with administering the DPNP—has to-date selected a "maximum fair price" for one drug that AbbVie manufactures: Imbruvica, which treats certain blood cancers. CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026*, https://tinyurl.com/2584m4h7.

113. The MFP for Imbruvica is set to go into effect on January 1, 2026. CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026*, https://tinyurl.com/mr4c67rz.

114. Separately, the DPNP contemplates that an individual eligible to receive the "maximum fair price" for a selected drug may sometimes (or even often) receive the drug at a 340B hospital or pharmacy, and the dispensed drug may also be subject to a pharmaceutical pricing agreement under the 340B statute. To that end, the DPNP contains an MFP-340B nonduplication provision. 42 U.S.C. §1320f-2(d). That provision obligates the manufacturer of a drug that is both subject to the "maximum fair price" and a pharmaceutical pricing agreement to provide ***only*** the lower of the two price concessions—but not both. *See id.*

115. CMS has disclaimed any responsibility for identifying and deduplicating MFP-340B dispenses. *See* CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Section 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027*, at 230 (Oct. 2, 2024), https://tinyurl.com/ychztdfu ("2027 Guidance") ("CMS will not, at this time, assume responsibility for nonduplication of discounts between the 340B ceiling price and MFP."); *id.* at 54 ("Neither CMS nor the [contractor facilitating data flow between CMS, manufacturers, and providers] will verify that a claim was or was not billed as a 340B-eligible drug.").

116. That leaves avoiding duplicate MFP-340B discounts in the hands of manufacturers like AbbVie. Indeed, that is precisely what CMS intends: "CMS strongly encourages manufacturers to work with dispensing entities, covered entities and their 340B TPAs, and other prescription drug supply chain stakeholders (e.g., wholesalers) to facilitate access to the lower of the MFP and the 340B ceiling price, wherever applicable." *Id.* at 232.

117. Claims data is the most accurate and efficient method of ensuring compliance with the DPNP's nonduplication provisions because it enables manufacturers to quickly identify which dispenses were both MFP- and 340B-eligible.

118. After widespread concern about the significant nonduplication issues facing manufacturers with both a selected drug and a pharmaceutical pricing agreement, HRSA issued a notice calling for applications to implement a rebate model for effectuating the 340B price to covered entities and contract pharmacies. *See HRSA, 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program*, 90 Fed. Reg. 36,163 (Aug. 1, 2025) (the "Pilot Rebate Program"). The Pilot Rebate Program arises primarily out of concerns addressed to "340B and Maximum Fair Price … deduplication" for manufacturers that have drugs subject to both price concessions. *See id.* at 36,164. The Pilot Rebate Program specifically contemplates that manufacturers will make the 340B price available through a rebate mechanism: Manufacturers will sell drugs to covered entities and contract pharmacies at the commercial price and later issue rebates for the difference between that price and the 340B price. *Id.* at 36,163. It also contemplates that manufacturers will request, and covered entities (and contract pharmacies) will submit, claims data for 340B dispenses in order to obtain a rebate. *Id.* at 36,164-65.

119. AbbVie is preparing an application with the expectation of participating in the Pilot Rebate Program. And either way, the Pilot Rebate Program confirms that the federal 340B Program encompasses the right of manufacturers to request claims data from covered entities and contract pharmacies.

STANDING

120. AbbVie is injured by H.B. 1473 because the statute will force AbbVie to convey significantly discounted drugs to commercial pharmacies that AbbVie would not otherwise convey and on terms AbbVie would not otherwise accept. In that way, the law forces AbbVie to provide its private property to another private party in a prohibited A-to-B wealth transfer.

121. H.B. 1473 also injures AbbVie because it imposes state-level requirements that directly conflict with and frustrate the federal 340B program. In other words, H.B. 1473 subjects

AbbVie to conflicting obligations, compliance burdens, potential enforcement actions, and also raises the costs of AbbVie's participation in federal healthcare programs. Moreover, the law subjects AbbVie to the North Dakota's enforcement of the Act's requirements. Plaintiffs are signatories to 340B PPAs, and/or are successors-in-interest to executed 340B PPAs, with HRSA.

122. AbbVie's injuries are fairly traceable to H.B. 1473 because the statute compels a private transfer of AbbVie's 340-discounted drugs to private, for-profit commercial pharmacies. There is no recognized public use or purpose for such a transfer. That transfer would not occur but-for the operation of H.B. 1473's prohibition on AbbVie's contract pharmacy policy. In addition, the statute seeks to impose new state law obligations on drug manufacturers participating in the 340B program beyond those required by the federal statute. Neither section 340B, nor any existing regulation, nor the PPA, contains these requirements. Moreover, the Act purports to grant the North Dakota Attorney General and Board of Pharmacy authority to enforce the Act in a way that violates federal law and would infringe on AbbVie's property rights.

123. A favorable ruling is likely to address AbbVie's injuries. Enjoining the provisions of H.B. 1473 that unconstitutionally force the taking of manufacturers' private property for no public use would redress AbbVie's injuries because AbbVie's property would not be unconstitutionally taken, and AbbVie would not be exposed to state-imposed penalties for exercising its rights under the 340B program and the Constitution. Similarly, a declaratory judgment would redress AbbVie's injuries because AbbVie would not be exposed to enforcement actions and accumulating penalties.

BASIS FOR INJUNCTIVE RELIEF

124. "Irreparable harm occurs when a party has no adequate remedy at law, typically because its injuries cannot be fully compensated through an award of damages." *Facility Guidelines Inst., Inc. v. UpCodes, Inc.*, 677 F. Supp. 3d 955, 975 (E.D. Mo. 2023) (quoting *Gen.*

Motors Corp. v. Harry Brown's, LLC, 563 F.3d 312, 319 (8th Cir. 2009)). Moreover, where costs are not recoverable because the government-defendant enjoys sovereign immunity from monetary damages, irreparable harm generally exists. *See Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2489 (2021) ("The moratorium [on collecting rent during COVID-19 pandemic] has put the applicants, along with millions of landlords across the country, at risk of irreparable harm by depriving them of rent payments with no guarantee of eventual recovery."); *see also Iowa Utls. Bd. v. FCC*, 109 F.3d 418, 426 (8th Cir. 1996) ("The threat of unrecoverable economic loss . . . does qualify as irreparable harm.").

125. Effecting an unconstitutional taking of AbbVie's private property in a forced transfer to another private party for no recognized public use or purpose constitutes an irreparable injury. *See Laclede Gas Co. v. St. Charles Cnty.*, 713 F.3d 413, 419-20 (8th Cir. 2013) (affirming grant of preliminary injunction on takings claim). A taking occurs each and every time that AbbVie is required against its own volition to transfer its drugs at the 340B-discounted price to a commercial pharmacy for the private benefit of that for-profit pharmacy.

126. Further, if H.B. 1473 is not enjoined as applied to AbbVie, AbbVie would be exposed to additional state law requirements as a condition of participating in the federal 340B program and would risk violating H.B. 1473 simply by performing its federally mandated functions. *See Brooks v. Francis Howell Sch. Dist.*, 599 F. Supp. 3d 795, 805 (E.D. Mo. 2022) ("Well-settled law holds that the loss of [constitutional] freedoms, even for minimal periods of time, 'unquestionably constitutes irreparable injury.'" (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976))). A party may be irreparably injured in the face of the threatened enforcement of a preempted law. *See, e.g., Craig v. Simon*, 980 F.3d 614, 617–18 (8th Cir. 2020); *see also Bank One, Utah v. Guttau*, 190 F.3d 844, 847–48 (8th Cir. 1999) (concluding that where the plaintiff

proves preemption and "that it will suffer irreparable harm if the State is not enjoined from enforcing [the preempted law], then the question of harm to the State and the matter of the public interest drop from the case, for [the plaintiff] will be entitled to injunctive relief no matter what the harm to the State, and the public interest will perforce be served by enjoining the enforcement of the invalid provisions of state law."); *Rogers Grp., Inc. v. City of Fayetteville*, 629 F.3d 784, 785, 789–90 (8th Cir. 2010) (affirming preliminary injunction in preenforcement suit alleging that a municipality's ordinance was beyond its powers under state law and finding a sufficient threat of irreparable harm where the plaintiff "admit[ted] that the Quarry currently operated at a level the Ordinance permitted" but "testified that the Ordinance would prevent the Quarry from expanding"); *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 160 (2014) (concluding that a plaintiff has standing to "bring a preenforcement suit when he has alleged an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder." (internal quotation marks and citation omitted)); *Ass'n for Accessible Medicines v. Ellison*, 2023 WL 8374586, at *6–7 (D. Minn. Dec. 4, 2023) (granting motion for preliminary injunction when the statute at issue was already in effect and movants were in compliance).

127. If drug manufacturers such as AbbVie are required to provide their drugs to contract pharmacies, the magnitude of the economic loss is beyond the capacity of North Dakota to compensate with damages. Discounted purchases under the program reached approximately $66.3 billion for fiscal year 2023 in the U.S. *See* Health Res. & Servs. Admin., *2023 340B Covered Entity Purchases* (Oct. 2024), https://tinyurl.com/56nzphvm.

128. Further, North Dakota's entire budget for 2023 through 2025 approximates $6.5 billion per year. *See* North Dakota 2023 – 2025 Budget Highlights, *available at*

https://www.omb.nd.gov/sites/www/files/documents/financial-transparency/state-budgets/2023-25-budget-highlights-brochure.pdf. That means that even if North Dakota's entire yearly budget were dedicated to covering AbbVie's losses from the sales the state now compels, it would still come up short. As such, the ordinary legal remedy of damages would be insufficient. *See Eastern Enters. v. Apfel*, 524 U.S. 498, 521 (1998) (plurality op.) (noting that the Supreme Court has considered injunctive relief where there is a "lack of a compensatory remedy").

129. Prospective injunctive relief is appropriate because of the ongoing nature of the infringement of constitutional rights resulting from H.B. 1473. The law effects a repeated and ongoing mandatory private wealth transfer of AbbVie's 340B-discounted drugs to private, for-profit commercial pharmacies for the private benefit of that pharmacy and for no recognized public use, in violation of the United States' Constitution. The law deprives AbbVie and other manufacturers of their federal rights under the actual terms of the 340B program. And H.B. 1473 threatens to impose significant penalties upon manufacturers if they do not capitulate to North Dakota's attempt to modify the terms of that federal program. The deprivation of constitutional rights constitutes irreparable injury for purposes of a preliminary injunction. *Planned Parenthood of Minn., Inc. v. Cit. for Community Action*, 558 F.2d 861, 867 (8th Cir. 1977) (citing Wright & Miller, Federal Practice and Procedure § 2948 (1973)); *see also Nichols v. Moyers*, 2013 WL 2418218, at *2 (E.D. Mo. June 3, 2013) ("[Plaintiff's] ongoing inability to exercise her fundamental [constitutional] right . . . shows that she is threatened with irreparable harm in the absence of injunctive relief."); Wright & Miller, Federal Practice and Procedure § 2948.1 n. 26 (2d ed. 1995) (collecting cases).

130. Granting injunctive relief here would not harm the State. It is well settled that a state "cannot be irreparably harmed by an inability to enforce an unconstitutional law." *Toigo v.*

Dep't of Health & Senior Servs., 549 F. Supp. 3d 985, 995 (W.D. Mo. 2021); *Rodgers v. Bryant*, 942 F.3d 451, 458 (8th Cir. 2019) (upholding the lower court's "imposition of a . . . preliminary injunction" where it found, among other things, that "preventing [a state] from enforcing a law that is plainly unconstitutional would cause no injury." (internal quotation marks omitted)); *Pavek v. Simon*, 467 F. Supp. 3d 718, 762 (D. Minn. 2020) ("[A] State has no interest in enforcing laws that are unconstitutional and an injunction preventing the State from enforcing the challenged [unconstitutional] statute does not irreparably harm the State." (internal quotation marks and citation omitted) (cleaned up)); *Hispanic Interest Coalition of Ala. v. Governor of Alabama*, 691 F.3d 1236, 1249 (11th Cir. 2012). Moreover, there is no evidence that uninsured and needy patients—in North Dakota or anywhere else—benefit from the use of contract pharmacies, and North Dakota has no legitimate interest in enriching commercial pharmacies at the expense of manufacturers and patients.

131. Granting injunctive relief would be in the public interest. The public has no legitimate interest in enforcing unconstitutional laws, particularly those that force a private property transfer for no public use or purpose. *See Fernandez v. St. Louis Cnty., Missouri*, 538 F. Supp. 3d 888, 903 (E.D. Mo. 2021) ("The public has no interest in enforcing an unconstitutional ordinance." (internal quotation marks and citation omitted)). By contrast, the public has a strong interest in preventing states from imposing unconstitutional requirements that force the transfer of private property for the private benefit of private commercial parties. *Nichols*, 2013 WL 2418218, at *2 ("[T]he Eighth Circuit has made clear that 'it is always in the public interest to protect constitutional rights.'" (quoting *Phelps–Roper v. Nixon*, 545 F.3d 685, 690 (8th Cir.2008))). Further, the public has a strong interest in enforcing federal law and not permitting states to change the requirements for participation in federal healthcare programs.

FIRST CLAIM FOR RELIEF

Prospective Injunctive Relief and Declaratory Relief – Violation of Takings Clause, U.S. Const. amend. V, cl. 4

132. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

133. The Takings Clause of the Fifth Amendment provides: "[N]or shall private property be taken for public use, without just compensation." U.S. Const. amend V.; *see also Chicago, Burlington & Quincy Ry. v. Chicago*, 166 U.S. 226, 234–35 (1897) (incorporating and making applicable to states the Takings Clause of the Fifth Amendment through the Due Process Clause of the Fourteenth Amendment).

134. The Takings Clause extends to both real and personal property. *Horne*, 576 U.S. at 358. It is not limited to instances when the government physically appropriates property for its own use through eminent domain. A taking can also occur through legislation and regulation that sufficiently deprives a user of its property rights. *See E. Enters. v. Apfel*, 524 U.S. 498, 529 (1998).

135. Under the Constitution, the government has no authority to force A-to-B transfers of private property for the benefit of private parties. *See Kelo*, 545 U.S. at 477 (explaining that "the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation"). Such private takings are always unconstitutional, since "[n]o amount of compensation can authorize such action." *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005); *Calder v. Bull*, 3 U.S. (3 Dall.) 386, 388 (1798) ("[i]t is against all reason and justice" to allow government to "take[] property from A. and give[] it to B").

136. "Whenever a regulation results in a physical appropriation of property, a *per se* taking has occurred." *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 149 (2021). Statutes or

regulations that mandate the physical transfer of personal property from one private party to another private party amount to an unconstitutional taking with or without just compensation.

137. H.B. 1473 appropriates AbbVie's property rights in its drugs for the private benefit of for-profit, commercial pharmacies. On its face, North Dakota's H.B. 1473 requires AbbVie to acquiesce in the "acquisition" of its drugs at discounted prices by commercial pharmacies. H.B. 1473 § 1(b)(1). If North Dakota requires manufacturers to provide their drugs to other private entities, including contract pharmacies, at below-market prices—by purporting to add that as a state-law obligation attached to the federal 340B scheme—then North Dakota is engaged in an impermissible per se violation of the Constitution's Takings and Due Process Clauses.[3]

138. In the alternative, H.B. 1473 effectuates a regulatory taking.

139. In *Penn Central Transportation Co. v. New York City*, 438 U.S. 104, 124 (1978), the Supreme Court recognized that a regulatory taking requires consideration of a flexible three-factor test: (1) the economic impact of the regulation, (2) the extent to which the regulation has interfered with investment backed expectations, and (3) the "character of the governmental action."

140. H.B. 1473's requirement that manufacturers permit contract pharmacies to acquire their drugs is constitutionally impermissible because it requires the physical acquisition of AbbVie's drugs by another private party for no public purpose or use; imposes significant financial losses on AbbVie and other manufacturers; interferes with drug manufacturers' reasonable

[3] In the alternative, if the term "acquisition" does not mean the kind of transfer AbbVie contends is a taking, then the term is ambiguous and void for vagueness. H.B. 1473's provision that says a manufacturer may not "[d]irectly or indirectly deny, restrict, prohibit, or otherwise interfere with the acquisition of a drug by a contract pharmacy on behalf of a covered entity" is unconstitutionally vague and does not provide drug manufacturers with fair notice as to what conduct is actually prohibited and invites arbitrary and discriminatory enforcement.

investment backed expectations; and serves no valid government purpose because it deprives manufacturers of the full use and control of their property on a continual basis for the commercial benefit of private parties.

SECOND CLAIM FOR RELIEF

Declaratory/Injunctive Relief – Federal Preemption Under the Supremacy Clause, U.S. Const. art. VI, cl. 2

141. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

142. Under the Supremacy Clause of the Constitution, federal law is "supreme . . . , any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. As a result, federal statutes and regulations properly enacted and promulgated can nullify or "override[] a [conflicting] state law" or local actions. *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 353 (2000). In other words, "where a state statute conflicts with, or frustrates, federal law, the former must give way." *Forest Park II v. Hadley*, 336 F.3d 724, 731-33 (8th Cir. 2003) (cleaned up) (concluding that the remedy plaintiff requested for a violation of state law "would be legally unwarranted if the state statutes are preempted"); *Oberkramer v. IBEW-NECA Serv. Ctr.*, 151 F.3d 752, 756 (8th Cir. 1988) (concluding the district court properly dismissed state common law claims which were preempted by federal law).

143. Preemption can take multiple forms: express preemption, field preemption, and conflict preemption. *Forest Park II*, 336 F.3d at 732.

144. Conflict preemption occurs where it is impossible for a private party to comply with both state and federal law and also where "the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby*, 530 U.S.

at 372–73 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)) (alterations omitted); *see also Forest Park II*, 336 F.3d at 733.

145. By restricting manufacturers' right to attach terms and conditions their federal offer, H.B. 1473 imposes obligations beyond those established by Congress. Federal law does not grant pharmacies unilateral authority to dictate the terms of purchase of manufacturers' discounted drugs. H.B. 1473 unlawfully removes manufacturers' right to set the terms for sales of 340B-priced drugs, forcing them to transfer their discounted drugs to any location authorized by a pharmacy—even if it contradicts federal law.

146. Congress specifically defined which entities qualify for 340B discounts and intentionally chose not to mandate manufacturer participation in contract pharmacy arrangements. *See AstraZeneca Pharms. LP*, 543 F. Supp. 3d at 60. North Dakota has no lawful authority to force manufacturers to transfer their drugs under the 340B program at deeply discounted prices to any entity, let alone commercial pharmacies that do not qualify as covered entities under the program. The carefully delineated obligation for manufacturers to offer 340B priced drugs to covered entities is lawfully imposed by federal law solely as a condition of a manufacturer's participation in federal healthcare programs. To the extent that North Dakota seeks to impose, through H.B. 1473, any substantive obligation on manufacturers beyond what federal law requires, that state law obligation is preempted by federal law. Further, H.B. 1473 grants commercial pharmacies unchecked authority over manufacturers' offers without federal authorization. This unrestricted power creates diversion risks, contradicting federal safeguards and forcing manufacturers to support it.

147. The replenishment model results in diversion, which the federal statute forbids. *See* 42 U.S.C. § 256b(a)(5)(B). Thus, H.B. 1473 is preempted to the extent it expressly and impliedly protects the use of the replenishment model, a practice clearly in conflict with Congress' mandates.

148. Additionally, federal law does not prohibit manufacturers from requesting claims data. H.B. 1473 imposes an absolute ban on requiring claim or utilization data, preventing manufacturers from engaging in federally permitted compliance efforts. *See* H.B. 1473 § 1(b)(3). By imposing a ban on the collection of claims data, H.B. 1473 creates an irreconcilable conflict with federal law and obstructs the objectives of the federal 340B program.

149. It is foundational constitutional law that States may not regulate Congress's creations. *See McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 159 (1819) (Marshall, C.J.). A state law may not change the conditions for participation in the federal Medicare and Medicaid programs. Any attempt by North Dakota to regulate in this area impermissibly changes the requirements for participating in the federal 340B program and nullifies the "natural effect" of federal law. *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372–73 (2000).

150. Another type of implied preemption is field preemption. Field preemption occurs when Congress "occupies an entire field" of regulation so comprehensively that it has "foreclose[d] any state regulation in the area, even if it is parallel to federal standards." *Arizona v. United States*, 567 U.S. 387, 401 (2012); *see also Crosby*, 530 U.S. at 372–73. Field preemption also occurs where Congress intends "to foreclose any state regulation in the area, even if it is parallel to federal standards." *Arizona*, 567 U.S. at 401.

151. The 340B program is a comprehensive federal healthcare program. Every detail of the 340B program is determined by federal law.

152. Most obviously, the 340B statute sets forth the maximum ***price*** manufacturers must "***offer***" and the covered entities entitled to such offers. 24 U.S.C. § 256b(a)(1)-(2) (setting forth the requirement to "offer" a particular "ceiling price"), (a)(4) (enumerating the types of healthcare providers entitled to an offer of the ceiling price). "Price regulation is exclusively controlled by the federal statute[.]" *Morrisey*, 2024 WL 5147643, at *10. And this federal "offer" requirement includes a degree of liberty for manufacturers to include non-price terms. *See Novartis Pharms. Corp.*, 102 F.4th at 460, 463.

153. Next, the 340B statute does not just speak to the price to be offered, but also to the ***mechanism*** through which manufacturers offer that price. In particular, the statute makes available either a "discount" method or a "rebate" method. 42 U.S.C. § 256b(a)(1). As indicated above, the meaning of that text—including the authority it does or does not create for HRSA and the rights and obligations it creates for manufacturers—is the subject of ongoing litigation in D.C. federal district court. *See Eli Lilly and Company et al. v. Kennedy et al*., No. 24-cv-3220 (D.D.C.); *Bristol Myers Squibb Company v. Kennedy et al.*, No. 24-cv-3337 (D.D.C.); *Sanofi-Aventis U.S. LLC v. U.S. H.H.S.*, No. 24-cv-3496 (D.D.C.); *Novartis Pharmaceuticals Corporation v. Kennedy et al.*, No. 25-cv-0117 (D.D.C.). In general, HRSA claims that it retains pre-approval authority over manufacturers' pricing mechanisms, whereas manufacturers contend that the statute leaves that determination to manufactures in the first instance and that, in all events, any decision to may take a rebate mechanism off the table altogether would be arbitrary and capricious. *See, e.g.*, *Eli Lilly and Company et al. v. Kennedy et al.*, No. 24-cv-3220 (D.D.C), Doc. 15-1. North Dakota's attempt to regulate the ***mechanism*** of manufacturer's offers is *sui generis* even among state contract pharmacy laws, further reinforcing that North Dakota's law is preempted multiple times over.

154. Finally, the 340B statute also establishes HHS as the sole ***enforcement*** authority of the 340B Program and instructs the agency to create and enforce compliance mechanisms. That includes the consequences for manufacturers who fail to comply with the 340B statute's pricing requirements. 42 U.S.C. § 256b(d)(1)(B)(vi) (providing for civil monetary penalties in the case of "overcharging" for 340B drugs), (d)(3) (calling for the creation of an administrative dispute resolution process for alleged instances of overcharging and other disputes). And the Supreme Court has stated that the statute vests *exclusive* enforcement authority in HHS. *Astra USA, Inc.*, 563 U.S. at 119–20. As such, "state enforcement of" the statute's pricing and eligibility requirements "would necessarily intrude on the federal scheme." *Morrisey*, 2024 WL 5147643, at *10.

155. North Dakota's new law explicitly inserts itself into this Congressionally created field.

156. ***First***, H.B. 1473 intrudes into federal pricing and eligibility by prohibiting manufacturers from declining to permit the acquisition of their drugs to ***contract pharmacies at a particular price***. *See Morrisey*, 2024 WL 5147643, at *9. Manufacturers violate laws like H.B. 1473 "not by withholding drugs from contract pharmacies, but by refusing the 340B discount when delivering [their] drugs to those pharmacies." *Id.* That the state law defines the drugs in issue as "340B drug[s]" confirms that H.B. 1473 is a price regulation: "***Price*** is what distinguishes between an 'ordinary drug' and a 340B Program drug—a fact that seems to be reflected in the [North Dakota] statute itself." *Morrisey*, 2024 WL 5147643, at *9 (emphasis added).

157. Moreover, H.B. 1473 was enacted in response to manufacturers' policies, which according to HRSA and HHS result in overcharges. But the federal statute does not authorize state regulation concerning 340B pricing and who is entitled to access manufacturers' drugs at

discounted 340B prices. It leaves no room for states to interfere with the carefully designed 340B program. *See Arizona*, 567 U.S. at 401 (holding that where Congress has occupied the field, state laws that impose additional obligations are preempted).

158. ***Second***, H.B. 1473 aims to short circuit the ongoing dispute between manufacturers and HHS regarding the extent of manufacturers' rights and obligations over pricing mechanisms—in particular, whether manufacturers may utilize a rebate model without HRSA's preapproval. North Dakota's new law says a manufacturer may not "[o]ffer or otherwise make available a drug in the form of a rebate, unless in the form of a discount at the time of sale and authorized under federal law." H.B. 1473 § 1(b)(5). North Dakota's problem is that the 340B statue already "authorize[s]"

159. ***Third***, leaving no stone unturned, H.B. 1473 also thrusts North Dakota directly into the established 340B oversight structure, thereby undermining federal enforcement authority in contravention of the Supreme Court's decision in *Astra*. 563 U.S. at 119–20. H.B. 1473 purports to grant the North Dakota Attorney General and the Board of Pharmacy substantive roles in the 340B program's administration and enforcement, despite and in conflict with the comprehensive compliance and enforcement regime Congress provided. Neither the Attorney General not the Board are the entities Congress tasked with enforcement of the 340B statute. "Congress . . . made HHS administrator of both the Medicaid Rebate Program and 340B Program." *Astra*, 563 U.S. at 120. State enforcement "would undermine the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Id.*

160. Congress not only defined who was entitled to administer the 340B program (the Secretary of HHS, who has lawfully delegated the authority to HRSA), it also delineated which tools were available to the Secretary to ensure compliance. The 340B statute defines which audit

procedures and ADR mechanisms are available under the 340B program for handling disputes among manufacturers and covered entities concerning program compliance. *See* 42 U.S.C. § 256b(d)(1)(B)(v), (3). Likewise, Congress outlined the penalties that apply to manufacturers who violate the statutory requirements under the 340B program and engage in "overcharging." *See id.* § 256b(d)(l)(B)(vi), (2)(B)(v). North Dakota's attempt to install an alternative compliance and enforcement regime, with different regulators and distinct penalties, conflicts with the procedures detailed in the 340B statute and the lawfully promulgated federal rules implementing the statute.

161. The difficulty of complying with varying state regulatory frameworks only increases as more states pass new and different laws relating to the 340B program. As of filing, at least 19 other states have already passed contract pharmacy laws akin to H.B. 1473. State laws such as those passed by Maryland, West Virginia, Mississippi, Minnesota, Missouri, Arkansas, Kansas, Louisiana, New Mexico, North Dakota, South Dakota, and Utah have material differences among and between themselves, complicating compliance by manufacturers and subjecting manufacturers to different and varying enforcement. *Compare* West Va. Code § 60A-8-6a (extending similar prohibitions to an "agent, or affiliate" of a manufacturer), La. Rev. Stat. § 40:2883 (prohibiting a manufacturer from "prevent[ing] or interfer[ing] with ***any patient's choice*** to receive such drugs from the 340B entity" (emphasis added)), NM H.B. 78, § 1(A)(4), 57th Leg., 1st Sess. (2025) (covering only entities "receiv[ing] federal grant funding"), *and* NE L.B. 168, § 3(1), 109th Leg., 1st Sess. (2025) (compelling delivery to "***any location***" authorized by a covered entity (emphasis added)). Some states, like North Dakota, prohibit requiring the submission of claims data while others do not. *Compare* Md. Health Occupations Code § 12-6C-09.1 (prohibiting restrictions on "delivery" or "acquisition" of "340B drugs") *with* H.B. 1473,

§ 1(b)(3) (restricting the collection of "any claims, encounter, or utilization data") *and* NE L.B. 168, § 3(2), 109th Leg., 1st Sess. (2025) (restricting the collection of "any claim data, utilization data, encounter data, medical data, purchasing data, or other data"). As these laws continue to accrete, administration of the 340B program and compliance with a patchwork of state laws, may become untenable, with potential catastrophic effects for the nationwide prescription drug industry. *See* Adam J. Fein, *EXCLUSIVE: The 340B Program Soared to $38 Billion in 2020—Up 27% vs. 2019*, Drug Channels (June 16, 2021), https://tinyurl.com/4jdjhh7u (analyzing HRSA data to find the 340B program accounted for "16% of . . . total U.S. gross sales of brand-name drugs at list prices" in 2020).

THIRD CLAIM FOR RELIEF

Declaratory/Injunctive Relief – Federal Preemption Under the Supremacy Clause, U.S. Const. art. VI, cl. 2

162. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

163. In addition to being preempted by the federal 340B statute, H.B. 1473 is preempted by HRSA's Pilot Rebate Program.

164. Conflict preemption occurs where it is impossible for a private party to comply with both state and federal law or where "the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby*, 530 U.S. at 372–73. (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)) (alterations omitted).

165. AbbVie is preparing an application to participate in HRSA's Pilot Rebate Program.

166. AbbVie meets the eligibility criteria for the Pilot Rebate Program because AbbVie has both a signed pharmaceutical pricing agreement with HHS and a signed DPNP "Agreement" with CMS for initial price applicability year 2026.

167. The Pilot Rebate Program contemplates that manufacturers will make the 340B price available through a rebate mechanism. The Pilot Rebate Program also assumes, and explicitly contemplates, that manufacturers may collect claims data under the 340B Program.

168. H.B. 1473's interference with the Pilot Rebate Program is twofold.

169. First, H.B. 1473 explicitly prohibits manufacturers from making the 340B price available through a rebate mechanism. *See* H.B. 1473 § 1(b)(5) (A manufacturer may not "Offer or otherwise make available a drug in the form of a rebate, unless in the form of a discount at the time of sale and authorized under federal law."). That squarely conflicts with AbbVie's participation in the Pilot Rebate Program—the very nature of which is that participating manufacturers will make the 340B price available through a rebate mechanism.

170. Second, North Dakota's new law makes it a class B misdemeanor for a manufacturer to "[r]equire a covered entity or contract pharmacy to submit any claims, encounter, or utilization data as a condition for acquiring or receiving a drug, unless the claims, encounter, or utilization data sharing is required by federal law." H.B. 1473 § 1(b)(3). The law thereby purports to prevent manufacturers from requiring basic claims and utilization data from covered entities. Yet that is precisely what the Pilot Rebate Program requires manufacturers to do. In other words, H.B. 1473 interferes with AbbVie's ability to participate in the Pilot Rebate Program because the Program contemplates AbbVie requesting and obtaining the very same claims data that H.B. 1473 prevents AbbVie from requesting and obtaining.

FOURTH CLAIM FOR RELIEF

Declaratory/Injunctive Relief – Due Process Clause, U.S. Const. art. XIV

171. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

172. The Due Process Clause of the Fourteenth Amendment provides that no State may "deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV, § 1. "Due process has two requirements": "that laws provide notice to the ordinary person of what is prohibited and that they provide standards to law enforcement officials to prevent arbitrary and discriminatory enforcement." *Postscript Enter. v. Whaley*, 658 F.2d 1249, 1254-55 (8th Cir. 1981); *see also United States v. Davis*, 588 U.S. 445, 451 (2019) ("Vague laws contravene the first essential of due process of law that statutes must give people of common intelligence fair notice of what the law demands of them."). While a civil statute is held to less stringent standards, even laws which impose only civil consequences must still undergo a "stringent vagueness test." *Video Software*, 968 F.2d at 6899-90 ("The degree of constitutional vagueness depends partially on the nature of the enactment.") (citing *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 499 (1982)); *see also Carolina Youth Action Project; D.S. by and through Ford v. Wilson*, 60 F.3d 770, 781 (4th Cir. 2023); *Manning v. Caldwell for City of Roanoke*, 930 F.3d 264, 273 (4th Cir. 2019) (en banc).

173. H.B. 1473's provision that says a manufacturer may not "[p]rohibit a contract pharmacy from dispensing a drug by denying access to the drug" is unconstitutionally vague and does not provide drug manufacturers with fair notice as to what conduct is actually prohibited and invites arbitrary and discriminatory enforcement. AbbVie's policy does not deny access to any drugs, it only limits a contract pharmacy's access to AbbVie's drugs ***at the 340B price.***

174. Further, H.B. 1473's provision that says a manufacturer may not "[i]nterfere with the ability of a covered entity or contract pharmacy to dispense a drug to an eligible patient of the covered entity" is unconstitutionally vague and does not provide drug manufacturers with fair notice as to what conduct is actually prohibited and invites arbitrary and discriminatory

enforcement. AbbVie has no way of knowing how a covered entity and contract pharmacy come to determine a patient's "eligibility" because AbbVie does not know what patient definition any particular covered entity or contract pharmacy is using. Generally, contract pharmacies do not know at the moment of dispensing whether a patient is 340B "eligible" or not, so it is not clear how a manufacturer *could* interfere with the "ability of a . . . contract pharmacy to dispense a drug to an eligible patient of the covered entity" in the first place. Nor, as explained above, is AbbVie permitted to seek utilization or claims data under H.B. 1473, further compounding the issue.

175. H.B. 1473 is unconstitutionally vague on its face. Persons of common intelligence must guess at the law's meaning and may well offer vastly different yet reasonable interpretations of its scope.

FIFTH CLAIM FOR RELIEF

Declaratory/Injunctive Relief – Commerce Clause, U.S. Const. art. 1 § 8

176. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

177. Central to our federal constitutional structure is the principle that "all States enjoy equal sovereignty." *Shelby Cnty. v. Holder*, 570 U.S. 529, 535 (2013). "A basic principle of federalism is that each State may make its own reasoned judgment about what conduct is permitted or proscribed within its borders, and each State alone can determine what measure of punishment, if any, to impose on a defendant who acts within its jurisdiction." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003) (citation omitted). This basic principle manifests in the several constitutional provisions that limit the power and authority of the states in relation to each other. *See, e.g.*, U.S. Const. art. I, § 10 (denying certain powers states otherwise might enjoy as sovereign nations); art. IV, § 1 (Full Faith and Credit Clause); art. IV, § 2, cl. 1 (Privileges and Immunities Clause); art. IV, § 2, cl. 2 (interstate extradition).

178. The Commerce Clause—which grants Congress the "Power . . . To regulate Commerce . . . among the several States," U.S. Const. art. I, § 8, cl. 3—also implicitly limits the extraterritorial authority of the States. The Supreme Court has held that the Commerce Clause prohibits states from directly "control[ling] commerce occurring wholly outside [its] boundaries." *Healy v. Beer Inst.*, 491 U.S. 324, 335–36 (1989); *see also Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986).

179. The Court recently clarified the reach of its "dormant" Commerce Clause jurisprudence, holding that state regulation of conduct within its borders that may also have an "extraterritorial effect" in other states are not categorically barred. *Nat'l Pork*, 598 U.S. at 374. But the Court also made clear that it did not disturb its prior precedent finding state laws unconstitutional where they "directly regulated out-of-state transactions by those with no connection to the State." *Id.* at 376 n.1 (citing *Edgar v. MITE Corp.*, 457 U.S. 624, 641–43 (1982)). As a result, a state statute may violate the dormant Commerce Clause in three ways: if it (1) "clearly discriminates against interstate commerce in favor of in-state commerce," (2) "imposes a burden on interstate commerce that outweighs any benefits received," or (3) "has the practical effect of extraterritorial control on interstate commerce." *Grand River Enters. Six Nations, Ltd. v. Beebe*, 574 F.3d 929, 942 (8th Cir. 2009).

180. H.B. 1473 runs afoul of dormant Commerce Clause principles on all three fronts.

181. ***First***, H.B. 1473 discriminates against interstate commerce in favor of in-state commerce. The central aim of North Dakota's law is to privilege state hospitals and pharmacies over out of state manufacturers by compelling manufacturers to provide drugs at significantly reduced prices to entities which would not otherwise be entitled to such discounts under federal

law. That significantly burdens out-of-state manufacturers like AbbVie for the direct benefit of in-state entities by compelling AbbVie to extend them bargain basement pricing.

182. North Dakota cannot articulate any valid justification for discriminating against out-of-state manufacturers. As detailed above, compelling AbbVie to transfer more drugs at reduced costs to contract pharmacies does not benefit 340B patients—it serves only to create arbitrage profits for commercial pharmacy chains.

183. ***Second***, H.B. 1473 imposes a burden on interstate commerce that outweighs any conceivable benefit to in-state commerce. *Davis*, 553 U.S. at 353 (2008).

184. H.B. 1473 places an improper thumb on the scale and tilts the bargaining power in favor of in-state pharmacies and covered entities at the expense of out-of-state manufacturers.

185. AbbVie and other manufacturers will have to contend with a patchwork of state 340B laws with different terms and requirements, each purporting to regulate transactions that are primarily nationwide in nature. For example, some states prohibit the collection of claims data while others do not. Others prohibit offering the 340B price through rebates while others do not.

186. It will be practically impossible for manufacturers like AbbVie to conform its contracts with nationwide wholesalers and distributors to overlapping and competing requirements of state law without creating conflicts and forcing violations of competing laws. *See Healy*, 491 U.S. at 336 ("[T]he practical effect of the statute must be evaluated . . . by considering how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation.").

187. As more states enacted their own 340B laws like H.B. 1473, the burden on interstate commerce—and in particular on out-of-state manufacturers like AbbVie—will snowball. AbbVie will have no choice but to conform to distinct and often conflicting 340B laws in each state—all

for North Dakota's purpose of privileging its own intrastate interests. *See Nat'l Pork*, 598 U.S. at 377 ("[T]he *Pike* line serves as an important reminder that a law's practical effects may also disclose the presence of a discriminatory purpose.").

188. The North Dakota Legislature's use of a federal program to benefit the in-state covered entities and contract pharmacies ***themselves*** at the expense of out-of-state manufacturers like AbbVie, would "amount[] to 'simple economic protectionism'" that the Supreme Court recently affirmed to be an illegitimate legislative interest. *Nat'l Pork*, 598 U.S. at 372 (quoting *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 580 (1986)). By protecting local economic interests at the expense of interstate commerce, North Dakota engages in economic protectionism, precisely what the dormant Commerce Clause doctrine aims to prevent.

189. But again, even if passed to help ensure 340B-eligible patients receive discounts on their prescription medications, H.B. 1473 will actually have the opposite effect. Manufacturers, no longer able to impose conditions on who actually receives their drugs, will be unable to stop abuses that result in covered entities requiring "insured patients to pay ***more*** for their prescriptions at contract pharmacies so the covered entity can generate 340B funds." Peter J. Pitts & Robert Popovian, *340B and the Warped Rhetoric of Healthcare Compassion*, Food & Drug L. Inst. Update Mag. (Fall 2022) (emphasis added), https://tinyurl.com/yc6fnc5c. H.B. 1473 provides no legitimate benefit to the State of North Dakota and thus cannot outweigh the high burden it places on the national drug industry and the 340B program itself.

190. ***Third***, H.B. 1473 has the practical effect of extraterritorial control on interstate commerce. *Styczinski v. Arnold*, 46 F.4th 907, 912 (8th Cir. 2022); *see Healy*, 491 U.S. at 324 (concluding that "a statute that directly controls commerce occurring wholly outside the

boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature"). Covered entities often enter contract pharmacy arrangements with pharmacies located outside the state. For example, a North Dakota covered entity may have contract pharmacies in Minnesota. And a Minnesota covered entity may have contract pharmacies in North Dakota.

191. The plain text of H.B. 1473 purports to reach all of these transactions occurring outside of North Dakota and thereby permits the Attorney General and the Board to use H.B. 1473 to regulate out-of-state manufacturers that conduct minimal to no business within the state. The statute bars pharmaceutical manufacturers from "[d]irectly or indirectly deny[ing], restrict[ing], prohibit[ing], or otherwise interfere[ing] with the acquisition of a drug by a contract pharmacy." H.B. 1473 § 1(b)(1). The statute then applies to any "manufacturer, an agent or affiliate of that manufacturer, virtual manufacturer, or third-party logistics provider of a manufacturer's drugs." H.B. 1473(1)(b). And it defines "contact pharmacy" as "a pharmacy that has a contract with a covered entity to receive and dispense drugs to the covered entity's patients on its behalf." H.B. 1473(1)(a).

192. H.B. 1473 thus purports to prohibit ***any*** manufacturer across the country from imposing conditions to the transactions between itself and ***any*** pharmacy across the country. Indeed, on its face, the North Dakota law could govern a transaction between a drug manufacturer located in Illinois and a California pharmacy that dispenses the drug to a patient of a North Dakota covered entity. In fact, it is not clear that the North Dakota law requires any nexus to North Dakota. Such broad reach results in North Dakota's improper interference with interstate commerce in violation of dormant Commerce Clause doctrine.

193. This extraterritorial reach will also pose a very high burden on the 340B program and the national prescription drug industry as a whole. Forcing manufacturers across the country to transfer their discounted drugs to any contract pharmacy authorized by any covered entity will result in transactions that may be fully permissible in the state where they actually occur but become subject to enforcement actions in North Dakota.

PRAYER FOR RELIEF

WHEREFORE, AbbVie prays for the following relief:

1. A declaration, order, and judgment declaring that H.B. 1473 effects an impermissible taking of AbbVie's property for private benefit;
2. A declaration, order, and judgment holding H.B. 1473 unlawful because it is preempted by federal law and unconstitutional under the Supremacy Clause;
3. A declaration, order, and judgment holding H.B. 1473 unlawful because it is unconstitutionally vague and fails to satisfy the requisite requirements of the Due Process Clause;
4. A declaration, order, and judgment declaring that H.B. 1473 violates the Commerce Clause;
5. A declaration, order, and judgment holding that the 340B statute does not require drug manufacturers to provide 340B pricing to contract pharmacies or transfer or cause their discounted covered outpatient drugs to be transferred to contract pharmacies;
6. A preliminary and permanent injunction enjoining the North Dakota Board of Pharmacy from enforcing H.B. 1473;
7. A preliminary and permanent injunction enjoining the North Dakota Attorney General from enforcing H.B. 1473;

8. An award of all costs and attorneys' fees pursuant to any applicable statute or authority; and

9. Any other relief that this Court deems just and proper.

Dated: September 5, 2025

Respectfully submitted,

/s/ Benjamin J. Sand

Benjamin J. Sand
CROWLEY FLECK PLLP
100 West Broadway, Suite 250
Bismarck, ND 58501
Telephone: 701.223.6585
Email: bsand@crowleyfleck.com

Matthew S. Owen, P.C. (admission granted)
Meredith M. Pohl (admission granted)
KIRKLAND & ELLIS LLP
1301 Pennsylvania Avenue N.W.
Washington, D.C. 20004
Telephone: (202) 389-5000
Email: matt.owen@kirkland.com
meredith.pohl@kirkland.com

Counsel for Plaintiffs.